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First, Do No Harm: Adverse Effects and the Need for Practice Standards in Neurofeedback

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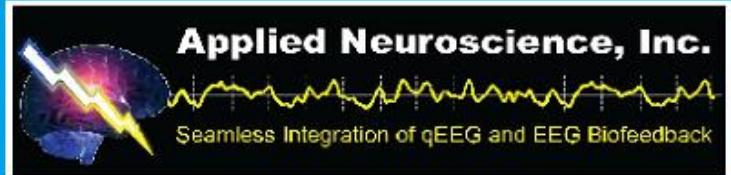
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ABSTRACT. Adverse and iatrogenic effects associated with psychotherapy have been substantiated in research for more than 40 years. Controlled research also exists in the field of neurofeedback (electroencephalographic biofeedback) that documents that negative effects can occur from inappropriate training. This article presents accumulating evidence, taken directly from acknowledgments by neurofeedback practitioners of the existence of both transient side effects and of more serious adverse reactions that have occurred. Unlicensed and unqualified practitioners pose a risk to the public and to the integrity and future of the profession. It is vitally important that both professionals and professional societies emphasize standards of practice and that the public be protected from individuals seeking to use neurofeedback to work with medical, psychiatric, and psychological conditions for which they are not qualified and licensed to work. Some in the field propose pursuing biofeedback or psychophysiology licensure as a means to establish standards of practice and address ethical concerns. This is a reasonable option to consider, although it may take many years to implement in various states. In the meantime it is vitally important that individuals offering neurofeedback services for clinical diagnostic conditions be licensed to lawfully provide services for such conditions.

KEYWORDS. Adverse effects, consumer protection, EEG biofeedback, iatrogenic effects, neurofeedback

INTRODUCTION

Bergin (1971) reported 30 research studies that documented deterioration in a proportion of patients who underwent psychotherapy. Within 6 years there were more than 40 studies identified that demonstrated

negative effects from therapy (Lambert, Bergin, & Collins, 1977). Bergin and Lambert (1978) defined such iatrogenic effects in these words:

Deterioration implies an impairment of vigor, resilience, or usefulness from

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a previously higher state. Generally, it has been regarded as a worsening of the patient's symptomatic picture, the exaggeration of existing symptoms, or the development of new symptoms, as assessed before and after treatment. (p. 152)

Clinical experience and research has found that neurofeedback has great therapeutic value (e.g., Hammond, 2006; Monastra, Monastra, & George, 2002; Peniston & Kulkosky, 1990, 1991; Sterman, 2000). However, it has been noted previously that side effects and adverse reactions can occur in association with neurofeedback treatment of various conditions (Hammond, Stockdale, Hoffman, Ayers, & Nash, 2001).

An abundance of evidence has demonstrated that there is a heterogeneity in the electroencephalography (EEG) patterns associated with various symptom complexes and diagnoses, whether it is a more common diagnosis such as attention deficit disorder/attention deficit hyperactivity disorder (ADD/ADHD; e.g., Monastra, 2005) or more complex and difficult to treat conditions such as obsessive-compulsive disorder (Prichet et al., 1993), schizophrenia (e.g., John, Prichet, & Alper, 1994), or autism (Sutton et al., 2005). Consequently, when treatment is not individualized following a conscientious assessment of not only symptoms but also of the brain's electrophysiological functioning, we believe that there is a greater risk posed of either being ineffective or of producing an iatrogenic effect. Everyone does not benefit from the same treatment or need the same thing, and in fact psychotherapy studies have long suggested that failure to individualize treatment is a significant risk factor for causing harm (e.g., Lieberman, Yalom, & Miles, 1973).

Ethical guidelines against trying to experimentally induce iatrogenic effects have limited the amount of research that we have available on adverse reactions. However, some hard evidence does exist. Lubar et al. (1981) published a reversal double-blind controlled study with epilepsy in which they documented that uncontrolled epilepsy could

either be improved with neurofeedback or be made worse if the wrong kind of neurofeedback training was done. It was likewise demonstrated by Lubar and Shouse (1976, 1977) that ADD/ADHD symptoms could both improve but also be made worse if inappropriate neurofeedback treatment was provided. This study used an A-B-A reversal design and established that when theta (4–7 Hz) was inhibited and the sensorimotor rhythm reinforced, improvements occurred in ADHD symptoms. However, when theta was reinforced, there was a deterioration and reversal of the positive improvements.

A double-blind, A-B-A crossover design study was conducted by Whitsett, Lubar, Holder, Pamplin, and Shabsin (1982) with uncontrolled epilepsy patients. This is one of the studies that importantly substantiated that neurofeedback does not teach the patient voluntary self-regulation of brain-wave activity but rather actually reconditions the manner in which the brain is functioning. Clinicians familiar with epilepsy are aware that there is more epileptiform activity found in the sleep EEG than in a waking EEG. In the Whitsett et al. (1982) study, sleep EEG was evaluated, and it was determined that training to inhibit theta activity and to enhance the sensorimotor rhythm (SMR) resulted in an 18% decrease in paroxysmal activity from a baseline of 72%. However, when the reward contingencies were reversed, there was a 29% increase in epileptiform activity (which, of course, was concluded to be detrimental to the patients), and then following a reinstatement of the appropriate treatment, there was a decrease of more than 60% in paroxysmal activity. These findings reinforce once again that inappropriate neurofeedback training can cause negative effects.

Incorrect assumptions about the most efficacious treatment protocols can certainly sometimes be made, particularly by less educated neurofeedback practitioners. We have heard some individuals express to the public that neurofeedback never results in adverse effects. As we have pointed out, this simply cannot be said. We have also seen practitioners assume that because quantitative EEG research has reported that

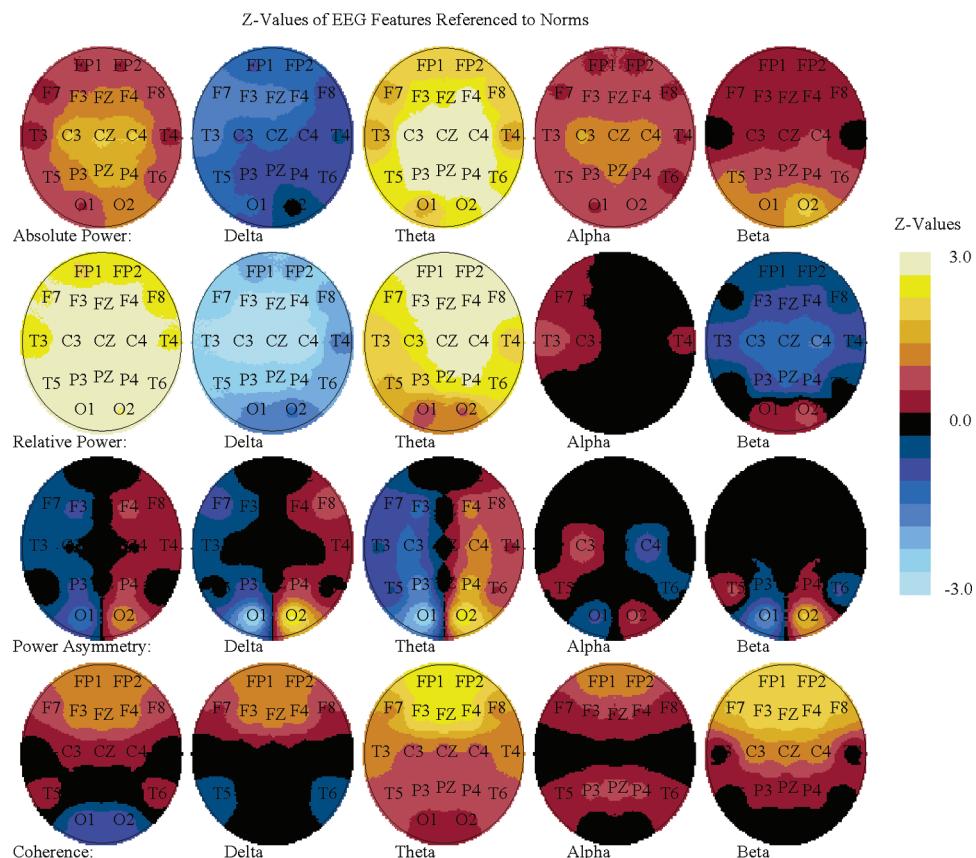
alcoholics commonly have an excess of beta activity and a deficiency of alpha and theta activity (e.g., John, Prichep, Fridman, & Easton, 1988) that, therefore, neurofeedback training to inhibit beta activity and reinforce alpha and theta is the treatment of choice for this population. The problem is that such an assumption rests on generalities and group averages that do not always apply to individual cases.

In the real world of clinical practice, comorbidities are common and patients can be unique. For example, Figure 1 displays the quantitative EEG (QEEG) map from the NxLink database for a 25-year-old chronic alcoholic patient. As can be seen, she displays an extreme excess of theta, not beta activity. This patient fits a subtype of 24% of alcoholics who have a diagnosis of ADHD (Schubiner et al., 2000). A lack

of individualization and use of an alpha/theta protocol in such a case could be anticipated to have the potential to seriously compromise cognitive function and result in even greater problems with impulse and emotional control. As we note later in this article, alpha/theta training, or perhaps we should say inappropriately applied alpha/theta training, has particularly seemed prone to producing some adverse effects.

We should similarly note that about 10 to 15% of ADHD patients have an excess of beta rather than theta activity (Chabot, Merkin, Wood, Davenport, & Serfontein, 1996; Clarke, Barry, McCarthy, & Selikowitz, 1998, 2001a, 2001b). Some practitioners, without having conducted individualized assessments, have simply assumed that ADHD patients will usually have an excess of theta activity and a deficit of beta.

FIGURE 1. Eyes closed EEG power of a chronic alcoholic patient who may also have ADHD as evidenced by abnormally elevated theta activity.



If the clinician then uses a canned protocol to increase beta activity in such a patient (who already has excess beta and cortical irritability), the patient could very well experience a seizure, anxiety, or tic activity.

THE NEED FOR MORE VIGOROUS STANDARDS OF PRACTICE

The authors have become increasingly alarmed about risks of iatrogenic harm and adverse reactions for two reasons. First, there have come to be an increasing number of dealers, manufacturers, and trainers who have been supplying EEG biofeedback equipment directly to laypersons. These individuals have no advanced degrees or health care licenses for independent practice, and yet many of them are opening practices and advertising to the public that they have competency to work with serious medical, psychiatric, and psychological problems, including depression, bipolar disorder, uncontrolled epilepsy, obsessive-compulsive disorder, traumatic brain injuries, stroke, autism, alcoholism, and drug abuse, as well as ADD/ADHD and learning disabilities. Some equipment and software manufacturers are seeking to “fly under the radar” of the Food and Drug Administration (FDA) and are evading registration of their equipment, whereas others are violating FDA regulations against the sale of biofeedback equipment to unlicensed individuals (or without the written prescription of a licensed practitioner).

Second, we have been impressed with the number of reports on public and professional internet list groups about side effects and adverse reactions. These effects range from very mild, transient symptoms such as fatigue or headache to much more serious conditions such as exacerbation of depression, manic episodes, emotional lability, seizures, and deterioration in cognitive functioning. Consequently, we believe that it is vitally important for legitimate and legally licensed practitioners to be aware of potential risks and for practitioners as well as professional societies to emphasize standards of practice. We also

believe that it is important that future neurofeedback research not only monitor rates of improvement and lack of change but also report the frequency of side effects, adverse reactions, and deterioration in functioning.

NEW DATA ABOUT ADVERSE REACTIONS FROM NEUROFEEDBACK TRAINING

Because research on negative effects of neurofeedback is difficult to conduct, the authors have compiled information from at least seven internet list groups where there have been reports on these forums of side effects and adverse reactions. In the material that follows we describe, and in some cases directly quote, from these reports. In every case, the identity of the list groups, equipment being used, and individual making the report have been left anonymous. We emphasize that these are actual reports of individuals using neurofeedback. The only changes made were in spelling out abbreviations or in punctuation. Headings have been added for the convenience of the reader in identifying types of adverse effects.

Emotional Lability and Vocal Tics

One practitioner “did eyes closed alpha theta” training and discovered that the patient became “very emotionally labile” after returning home. Another practitioner described a 7-year-old patient who came for help with developmental articulation. They began by training beta at C3 and after two sessions added training at C4 because his sleep was being disturbed by the training. They then shifted training to C3-C4, but after several sessions the mother commented that she did not notice any improvements. The practitioner added bipolar training at C4-PZ, and after two sessions the mother said that her son was crying very easily. Therefore, the practitioner changed training to F3 “for the articulation and to reverse crying,” but instead of improving articulation the two sessions of training at F3

created a vocal tic. At this point the practitioner admitted that treatment ended because the mother was “afraid to bring him back,” but her son continued to have the iatrogenically developed tic. After all of this trial-and-error guesswork, the practitioner asked for advice in the event the child returned.

Deterioration and Loss of Improvements

“Most of the meth addicts with whom I have worked have had excessive alpha. In the past, when working with people with excessive alpha, I have not had good results with alpha/theta training, even after doing 20–30 eyes open training [sessions with another protocol] prior to the alpha/theta training. This group did well with the eyes open [training], but as soon as I switched to alpha/theta training, they lost most of the gains they had made. I then trained the alpha down and they quickly returned to the level of function prior to the alpha/theta theta training. As a result, I have avoided doing alpha/theta training with the addicts who have excessive alpha. Instead, when working with meth addicts I have done a lot of eyes open suppressing alpha, often over Cz, with excellent results.”

Regression

A mother doing home training with her autistic child acknowledged, “Adverse events happen from neurofeedback—at least in my home. My son regressed dramatically from the wrong training when we started 4 years ago.” This smart mother then continued, “But even with 3 years of home training, I would never train him without supervision.” Nash has also noted a case of decompensation in a borderline or fragile patient (Hammond et al., 2001).

Somatic Symptoms

A mother described an experience where interhemispheric training was done, with dominant electrocardiogram artifact present.

Immediately following the session he “became very ill, sick to his stomach and terrible headache within an hour of leaving.” Another practitioner reported that following a session a patient experienced nausea, a very bad headache, worsening of tinnitus, and disturbed equilibrium. Examples have also been given of patients where frontal beta uptraining has resulted in their increasing their facial muscle activity with a resulting increase in headaches.

Muscle Twitches

Another practitioner described that after a period where a 6-year-old child seemed to have calmed down, he then began “exhibiting jerking and a progression of muscle twitches, going rhythmically through the body.” A different highly experienced (but unlicensed) practitioner replied, “I believe you might have increased this reactivity. He sounds like the bipolar children I deal with. Definitely training too high [a reward frequency] can increase muscle twitches.”

Emotional Lability and Explosiveness

An experienced practitioner indicated having found that with right prefrontal neurofeedback training where they “rewarded beta and SMR frequencies” (e.g., at T4-Fp2) that it had precipitated “emotional meltdowns or explosions.”

Tics

In response to a question about whether neurofeedback could cause or worsen tics, a practitioner responded, “I suggest being very careful with left side training as I have seen tics increase and come back with [neurofeedback].” Another practitioner described reducing tics in a patient, but then after two to three training sessions at Cz, the tics were exacerbated, but further training reduced them again. Still another practitioner described the development of tics that consisted of mouth movements (such as licking his lips) after training that

reinforced a low frequency. There have also been cases of Tourette's where tics have increased.

A case of tics/Tourette's and inadequate history gathering. A practitioner described treating a 13-year-old boy who started "clearing his throat" and "making a sniffing sound" in combination shortly after he was put on Adderall. After he was taken off the medication, the tics continued. After 18 neurofeedback sessions the tics had decreased, and then the practitioner changed the protocol for another 8 to 10 sessions, resulting in still further improvement. "For some reason, I added [training at site] CZ to the mix," and tic frequency increased. The practitioner then learned that "the boy was born without a soft spot in his skull and that he had seizures as a child. He also would sway his head from side to side as a child and did so until the last few years. After treatment with a CZ [placement], he started doing this as he walked out of the office."

Incontinence

A highly experienced practitioner wrote, "I have had good results with stress incontinence with NF [neurofeedback]. This is important for all of us doing NF because training too low [a reward frequency] in vulnerable people can increase stress incontinence. We need to track this post-stroke or in older clients." Another practitioner admitted, "I caused bedwetting by going too low [in the reinforcement band]."

Enuresis

A practitioner described working with a 7-year-old boy with a previous history of bedwetting but who had not experienced enuresis in 1 year. After about 10 neurofeedback sessions he began having enuresis again. The protocol used prior to the resumption of bedwetting was a broad ("squash") protocol inhibiting 15 to 38 Hz at C3 and F3, which also resulted in whiny behavior. After his most recent neurofeedback session, the little boy awakened

the next morning and asked his mother, "Why do I always wet the bed after brain training?"

Mental Fogginess and Cognitive Inefficiency

"One reason a practitioner might have to deviate from just doing T3–T4 [training] is because of people who respond to that site like I do—at any frequency, just too disorienting and I have brain fog for two days." Another experienced practitioner utilizing a "one-size-fits-all" neurofeedback system in its default mode reported, "[The neurofeedback system] is supposed to make people aware of the present moment. But I, and most clients, get zoned out. Semi-conscious. It takes people a little while to recover from being groggy. We ask, 'Are you okay to drive?'" This posttreatment sedation symptom has been previously reported in the literature with Stockdale noting cases of patients where alpha/theta training had created "spacey" feelings or evoked traumatic memories (Hammond et al., 2001).

Further examples of mental fogginess and cognitive disorientation. Yet another well-known practitioner in the neurofeedback field reported the following after alpha/theta training: "In one case a client drove the car up on a curb after leaving the office; another drove through a red light; another slid through a stop sign at an intersection; and a fourth ran into a light pole only one block from his therapist's office following his first A/T session. Oh, yes, and a fifth went home and could not put two threaded pipes together, being momentarily spatially disoriented. In each of these cases the people involved said in retrospect that it was unlike them to behave that way." Imagine the potential liability! Yet another advanced practitioner described how he experimented on himself, rewarding delta activity. The result was the development of significant cognitive impairments that required a considerable number of neurofeedback sessions to remediate.

Another clinician described experimenting on himself with LORETA neurofeedback

for a problem with chronic pain. He decided to train the dorsal anterior cingulate and/or the right insula. "I tried rewarding different frequencies. There was some indication from a research study that one might train theta. When I tried this, my thinking got horribly foggy and I had to stop. I tried training 12 to 15 Hz, and could get no learning curve. I did best with 14 to 18 Hz, and that improved my attention back to normal, but I didn't notice any difference in pain."

Another case of cognitive inefficiency. A practitioner asked for help with a client with presenting complaints of insomnia and anxiety, which was assumed to mean "overarousal" Following an "optimum frequency evaluation" at T3-T4, "we began training at 3 to 6 Hz [reinforcement] which seemed to be the most positive, but she seemed to be very sensitive and not have a lot of emotional involvement so we trained at C3-C4 instead of T3-T4, and I removed the inhibits. Initially, this seemed to be decreasing her anxiety and she began sleeping better. This week however, she complains of grogginess and lethargy, forgetfulness, so I moved up in frequency and at 18 to 21 Hz she felt more alert. Today she's still groggy, forgetful, so I replaced the inhibits and gave her a little training at F7 F8 to help with memory. She left still feeling groggy." The practitioner reported that the woman was not ADD and "her forgetfulness does not seem to be related to inattention issues." Rather, she was an "extremely busy, productive person" who could not stand the "grogginess" that training had produced.

Sleep Disturbance

"I would appreciate some feedback in regards to a youngster I am currently working with. He has been diagnosed with mild to moderate autism. I have used neurofeedback with this population before with pretty good success. With this individual I have been training up SMR on the right side. The problem is his mother says his sleep patterns have become disturbed, i.e., waking up in the middle of the night and not going back to sleep for one or two hours. This

was not a pattern before neurofeedback." There have been other reports that an excessive amount of training with a disentrainment type of neurofeedback has sometimes resulted in a patient feeling "wired" and having difficulty falling asleep. In one case a patient was up all night without being able to sleep.

OCD Symptoms

"Has anyone seen OCD-like behavior result from downtraining 3-7 (Hz)? A boy I met recently had about 40 sessions of that training at F3, F4, CZ, T4, FP1, and FP2 (referential montages). He came with a QEEG that indicated the training I listed. His main reason for training prior to his recent issues was ADD, which still seems evident. He is 13 years old, above-average intelligence, psychological testing indicates ADD inattentive [type]; no significant learning disabilities. His mother feels his OCD-like stuff resulted from his training." Another seasoned practitioner reported seeing patients who had been trained by other practitioners for a lengthy period with a single protocol focused on beta activation who became very single-focused and obsessive.

Fatigue

A considerable number of practitioners have reported transient fatigue, lasting up to the remainder of the day following a neurofeedback session.

Seizure

An experienced practitioner, using neurofeedback with a reinforcement band in the theta or delta range, had a patient with no prior seizure history experience a seizure during training.

Anxiety, Agitation, Irritability, Rage, Depression, or Manic Reactions

Excessive reinforcement of beta during neurofeedback has been reported to cause

temporary irritability, anxiety, and sleep disturbance until the level of beta reinforcement was lowered. Recently an OCD patient contacted one of the authors. She had gone through 33 sessions of neurofeedback with a chiropractor, and not only did OCD symptoms not improve, but now she indicated that she was experiencing anger and rage reactions. One autistic boy experiencing a disentrainment type of neurofeedback was "wired," running around the house for 2 hours following a session. Another practitioner noted cases where SMR training created agitation and where "overtraining" exacerbated manic or depressive symptoms in bipolar disorder patients. One practitioner described inhibiting SMR in himself, which resulted in hyperactivity. Increased depression has also been reported.

Slurred Speech

An individual who described themselves as "articulate," reported that although they slept better, they were now experiencing slurred speech following neurofeedback.

DISCUSSION AND CONCLUSIONS

The reports we have cited are uncontrolled case reports from which, first, we cannot know the degree to which other confounding events in the patients' lives may have contributed to these negative symptoms and, second, we do not know whether the adverse symptoms were short lived or more enduring. After our review of descriptions of adverse reactions, it is our impression that a large percentage of negative effects and transient side effects may result from approaches to training that seek to reinforce and increase various bands of EEG activity (whether it is alpha, theta, beta, or delta), as opposed to focusing more on inhibiting or disentraining problematic EEG activity. Some individuals have also begun reinforcing very slow brainwave activity, which we believe may pose greater risks of side effects and which we hypothesize may produce more transient state changes that

appear calming in the short term, rather than enduring positive (trait) changes in the EEG. It has also been reported that coherence training has potential to create adverse reactions if not carefully monitored. The authors further believe that home training that is not regularly supervised by qualified professionals also increases the risk of negative effects.

Neurofeedback is an exceptionally valuable therapeutic modality, but this review has shown that it can also occasionally result in side effects, and when improperly done may in fact sometimes result in more significant iatrogenic reactions and an exacerbation of symptoms. Adverse effects that have been reported by clinicians include increased anxiety and agitation, panic attacks, manic-like behavior, headaches, nausea, fatigue, sleep disturbance, anger and irritability, crying and emotional lability, incontinence, enuresis, an increase in depression, decline in cognitive functioning (decreased concentration, mental fogginess), increase in obsessional rumination and OCD symptoms, increase in somatic symptoms (including tics and twitches), vocal tics, seizures, slurred speech, loss of previous symptomatic improvements, and temporary disorientation or dissociation that could put someone at risk for an accident or injury.

It is apparent that neurofeedback is a therapeutic modality that requires clinicians to be vigilant in watching for occasional side effects. Legitimate professionals should acknowledge to patients in an informed consent process that a side effect can occasionally occur, and less frequently that adverse reactions have occurred. Thus patients should be told that it is vitally important to report any side effects immediately should they occur so that training may be modified. We have found it useful to ask patients during and after sessions, and at the beginning of each new session, about any side effects (even though they may not be extremely frequent) and to have the patient rate symptoms on a 0 to 10 scale at the beginning of each session to facilitate discussion and the tracking of progress. When such careful monitoring is done, side effects are usually minor and infrequent because the clinician

can immediately modify training protocols before any negative effects escalate.

When clinicians are conducting alpha/theta or other types of deep relaxation training, we also consider it very important to ensure at the end of the session that patients feel sufficiently clear-headed to drive and function prior to allowing them to leave the office. The possibility of negative effects will also undoubtedly be minimized when practitioners obtain a thorough history of psychological and medical symptoms and employ assessment procedures prior to treatment, thus allowing for individualization. Ethical standards also require that one seeks consultation when problems arise and there is uncertainty about how to address them.

We strongly believe that the field of neurofeedback is at risk. Increasing numbers of lay persons are inappropriately and illegally obtaining neurofeedback equipment. A significant number of such persons are presuming that they are qualified to put electrodes on someone's head and to seek to alter the brain functioning of individuals with serious medical and psychological conditions. Serious consumer protection issues are involved. Not only do such lay practitioners have the potential to harm members of the public, as well as to be ineffective, but such individuals also place in jeopardy the future of the neurofeedback profession because such practices will undoubtedly result in legal actions for harm done (one current case is pending) and the disparagement of the field by physicians, psychologists, other licensed professionals, and the public at large in reaction to unqualified practitioners.

We therefore believe that it is incumbent upon licensed professionals to report lay practitioners to state regulatory bodies as practicing psychology and medicine without a license when they are found to be offering services for medical, psychiatric, and psychological conditions. Likewise our professional societies and members of those societies should not be admitting individuals to clinical training workshops unless they are licensed for independent practice, have a letter from their graduate school advisers in accredited institutions, or can verify through a letter from their employer

that they are a technician whose work is being supervised by a licensed professional. Similarly, allowing lay practitioners to be listed under "provider" sections of society websites places professional societies in the position of implicitly sanctioning and in a sense recommending to the public the unlawful practice of such individuals. It is imperative for both clinicians and professional societies to more actively educate the public about how to select qualified neurofeedback practitioners. One of the authors recently published such an article citing the value of neurofeedback, the need for licensed professionals to be adequately trained and certified, and importance of consumer protection (Hammond, 2008). Providing members of the public with copies of Hammond (2006) can be helpful in regard to public education.

Competency and continuing education must likewise be encouraged. Licensed clinicians should be strongly encouraged to obtain certification in neurofeedback (e.g., from the Biofeedback Certification Institute of America), and when they are analyzing their own quantitative EEG's, to pursue certification from the EEG and Clinical Neuroscience Society or the Quantitative Electroencephalography Certification Board or a credential from the Society for the Advancement of Brain Analysis. The protection of the public and of our profession requires that we more vigorously emphasize standards of practice. It is our opinion that it is unethical for practitioners to use neurofeedback to work with any medical, psychiatric, or psychological symptoms and conditions that they are not qualified to work with through both their training in other therapeutic modalities and by virtue of their licensure within their state or province.

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