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Ethical and Legal Considerations of Alternative Neurotherapies

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Abstract

Neurotherapies for diagnostics and treatment—such as electroencephalography (EEG) neurofeedback, single-photon emission computerized tomography (SPECT) imaging for neuropsychiatric evaluation, and off-label/experimental uses of brain stimulation—are continuously being offered to the public outside mainstream healthcare settings. Because these neurotherapies share many key features of complementary and alternative medicine (CAM) techniques—and meet the definition of CAM as set out in Kaptchuk and Eisenberg—here we refer to them as "alternative neurotherapies." By explicitly linking these alternative neurotherapy practices under a common conceptual framework, this paper draws attention to, and critically considers, the cross-cutting ethical and legal issues related to the provision of these services. The first section of this paper provides an updated empirical overview of uses of SPECT neuropsychiatric evaluations, EEG neurofeedback, and experimental/off-label forms of brain stimulation. Next, drawing on CAM bioethics scholarship, we highlight the pertinent ethical issues in the alternative neurotherapy context, including the truthful representation of evidence base, marketing to vulnerable populations, potential harms, provider competency, and conflicts of interest. Finally, we consider the principal legal issues at stake for the provision of alternative neurotherapies in the U.S., namely those related to licensing and scope-of-practice considerations. We conclude with recommendations for future research in this domain.

Keywords

Alternative medicine; brain stimulation; neurofeedback; neuroimaging; neurotherapies

INTRODUCTION

Neurotherapies for diagnostics and treatment are continuously being offered to the public outside mainstream healthcare settings. For example, even though single-photon emission computerized tomography (SPECT) imaging is not sanctioned by any professional physician society for use as a neuropsychiatric diagnostic, it is being marketed by the Amen Clinics and others for these purposes (Anderson, Mizgalewicz, and Illes 2013; Chancellor and

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Chatterjee 2011; Farah and Gillihan 2012). Electroencephalography (EEG) neurofeedback is offered by hundreds of practitioners in the United States (U.S.) to treat a variety of clinical indications, even though there is little evidence of efficacy for many of its advertised uses (Thibault et al. 2015; Thibault and Raz 2016; Wexler et al. 2020). Furthermore, a variety of experimental brain stimulation techniques, such as transcranial direct current stimulation (tDCS) and off-label transcranial magnetic stimulation (TMS), are often offered by providers that lack medical training (Wexler 2020) and by those that self-identify as practicing holistic and integrative medicine.

In this paper, we suggest that the abovementioned services share key commonalities that merit their conceptualization as part of a larger phenomenon. First, their use is not accepted as standard of care by mainstream medicine, nor is it sanctioned by professional physician societies. Second, the therapies utilized are not typically reimbursed via health insurance. Third, while there may be preliminary research supporting the use of a neurotechnology technique for some advertised indications, the evidence is typically not robust, rigorous, or conflict-free. Fourth, provider training—both in terms of medical background as well as proficiency with neurotechnology devices and techniques—may vary widely. Fifth, many (but not all) providers describe their practices as alternatives to mainstream medicine.

Notably, therapies that meet the criteria above are often referred to as complementary or alternative medicine (CAM; Ernst, Cohen, and Stone 2004; Ernst and Smith 2018). Though the exact definition of CAM varies considerably (Hufford 2003; IOM 2005; Mertz 2007), it broadly refers to therapies that either complement, or provide alternatives to, traditional ones (NCCIH 2018; Wilkinson 2013). According to the taxonomy set forth by Kaptchuk and Eisenberg (2001), CAM includes medical systems (e.g., acupuncture, homeopathy, and naturopathy), alternative dietary practices (e.g., nutritional supplements and macrobiotics), New Age healing (e.g., energies, Reiki, and crystals), mind-body therapies (e.g., hypnosis and meditation) and “non-normative scientific enterprises” wherein practitioners advocate “theories and practices unacceptable to the general scientific community” (Kaptchuk and Eisenberg 2001). As Kaptchuk and Eisenberg (2001) note, techniques in this latter category often utilize “unvalidated diagnostic methods” and “unconventional technological devices,” and may blur the boundaries between accepted and unaccepted off-label uses.

Though this latter category of “non-normative scientific enterprises” is not included in many definitions of CAM—it is absent, for example, from that utilized by the National Institute of Health’s National Center for Complementary and Integrative Medicine (NCCIH 2018)—it is the one most closely related to SPECT neuropsychiatric evaluations, EEG neurofeedback, and off-label/experimental uses of brain stimulation. These neurotherapies differ from other CAM techniques in that they appeal to scientific advances in neurotechnology rather than alternative medical systems or New Age healing practices. In addition, they utilize devices employed by mainstream scientists and physicians, albeit in unconventional ways. For example, while EEG and SPECT are routinely used by neurologists as a part of clinical practice, neurotherapy providers derive added meaning from the brain recordings, interpreting them as evidence of behavioral abnormalities and disorders. Thus, as a whole, the abovementioned neurotherapies derive in part from modern neuroscientific advances, but depart in that their use has been considered by traditional scientific and medical

communities to be premature (Chancellor and Chatterjee 2011), unproven (Farah and Gillihan 2012), experimental (Thibault, Lifshitz, and Raz 2016), or "mal-use" (Horvath et al. 2011).

Because these neurotherapies share many key commonalities of CAM services—and meet the definition of the "non-normative scientific enterprises" category of CAM as set out in Kaptchuk and Eisenberg (2001)—in this paper we refer to them as "alternative neurotherapies." Our use of this term is further supported by the manner in which many providers of these services define themselves. For example, in previous empirical work, we found that nearly three-quarters of websites of neurofeedback providers in our sample utilized language that is commonly defined as CAM-related, such as "alternative," "integrative," or "holistic" (Wexler et al. 2020). Similarly, in the realm of off-label TMS, our scoping review found that many providers of off-label TMS utilize this same terminology. And even amongst those who do not explicitly utilize language related to CAM—such as the Amen Clinics—it is not uncommon to find other CAM techniques being offered (e.g., hyperbaric oxygen therapy, infrared light therapy, and IV nutrient therapy; see Appendix A in IOM 2005), as well as the positioning of the therapy in opposition to mainstream medicine (e.g., as going beyond "traditional psychiatry," or as "unlike traditional psychiatry"; Amen Clinics 2020a).

By explicitly linking SPECT diagnostics, EEG neurofeedback, and off-label/experimental uses of brain stimulation under a common conceptual framework, this paper outlines the cross-cutting issues that span the provision of alternative neurotherapies. In what follows, we draw upon extant bioethics literature regarding the provision of CAM to critically consider the ethical and legal issues related to alternative neurotherapies. The first section of this paper provides an updated empirical overview of uses of SPECT neuropsychiatric evaluations, EEG neurofeedback, and experimental/off-label forms of brain stimulation. Next, drawing on CAM bioethics scholarship, we highlight the pertinent ethical issues in the alternative neurotherapy context. Finally, we consider the principal legal issues at stake for the provision of alternative neurotherapies in the U.S. and conclude with recommendations for future research in this domain.

ALTERNATIVE NEUROTHERAPIES

This paper discusses only those therapies that are provided in-person by practitioners to clients or patients, though at least two neurotherapies, EEG neurofeedback and tDCS, are also offered directly to the public without practitioner involvement, via the sale of home devices (Wexler 2018; Wexler and Thibault 2019). In addition, while we recognize that some traditional psychotherapies may indeed rely on neuroimaging data (e.g., to provide indirect evidence that a therapy is effective; see Linden 2006), here we have chosen to focus on therapies for which brain recording (or stimulation) forms the key component of the treatment or diagnostic. From our ongoing observations in this domain, we have selected three alternative neurotherapies that appear to be most prominent: SPECT diagnostics, which has been critiqued previously in the academic literature (Adinoff and Devous 2010; Alpert 2012; Anderson, Mizgalewicz, and Illes 2013; Chancellor and Chatterjee 2011; Farah 2009; Farah and Gillihan 2012); EEG neurofeedback, for which there are ongoing debates

about efficacy for the treatment of clinical indications (Micoulaud-Franchi and Fovet 2018; Schabus et al. 2017; Thibault, Lifshitz, and Raz 2017a; 2017b; Thibault and Raz 2017; 2018) and brain stimulation techniques that are either unapproved by the FDA, such as tDCS (Wexler 2020), or promoted by practitioners for off-label uses, such as TMS.

We have selected these three neurotherapies not only because each appears to be offered by numerous clinics (at least in the U.S.), but also because each touches upon a distinct neuroscience modality: neuroimaging, neurofeedback, and neurostimulation. We acknowledge that there are dozens of lesser-known neurotechnology techniques and devices utilized in ways that are not accepted by mainstream medicine. In principle, many, if not all, of these other alternative neurotherapies would be subject to the same ethical and legal framework outlined in this paper.

SPECT Diagnostics

In traditional health care settings, SPECT imaging is typically used to evaluate neurological diseases, such as stroke, epilepsy, and neurodegenerative disorders (ACR 2016). The SPECT imaging procedure consists of an IV injection of radioactive material, followed by a nuclear scan of the radioactive material in the brain (Cedars Sinai 2019). There are at least a dozen clinics in the U.S. offering SPECT scans for neuropsychiatric diagnostics and evaluations, such as CereScan, PathFinder, Neuro-Luminance Inc., DrSpectScan (CereScan 2020; DrSpectScan n.d.; Neuro-Luminance Inc. 2019; PathFinder 2020), and the eight locations of the Amen Clinics (2020b). At the Amen Clinics, the cost of an initial SPECT evaluation is approximately $4,000 (A. Nagappan, personal communication, July 24, 2020). The Amen Clinics claim that SPECT is useful both in the diagnosis of recognized clinical conditions listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM) such as bipolar disorder, panic disorders, and attention deficit disorder (ADD), as well as their own variations of such conditions, such as the “Ring of Fire ADD,” “Overfocused ADD,” and “Limbic ADD” (Amen Clinics 2020c). In addition, a few clinics make more general promotional statements about the use of SPECT to improve brain health (DrSpectScan n.d., Cerescan 2020.).

Concerns about the use of neuroimaging (and SPECT in particular) for diagnostic purposes have been raised in both academic outlets (Adinoff and Devous 2010; Alpert 2012; Anderson, Mizgalewicz, and Illes 2013; Chancellor and Chatterjee 2011; Farah and Gillihan 2012) and in the popular press (Hall 2007; Rubin 2007; Tucker 2012). Critiques have centered on the inherent challenges of using neuroimaging to diagnose psychiatric disorders, such as the difficulty of applying research that compares averaged patterns of brain activation to individuals, as well as the fact that psychiatric diagnoses are made on the basis of behavioral symptoms, many of which overlap across disorders (Chancellor and Chatterjee 2011; Farah and Gillihan 2012). Thus, at present, SPECT is not recommended by the American Psychiatric Association (APA) for neuropsychiatric diagnostic purposes. In 2005, the APA released a resource document stating that “the available evidence does not support the use brain imaging for clinical diagnosis or treatment of psychiatric disorders” (APA 2005). This document was followed by 2012 and 2018 APA consensus papers, both of

which stated that “there are currently no brain imaging biomarkers that are clinically useful for any diagnostic category in psychiatry” (APA 2012; APA 2018).

EEG Neurofeedback

EEG neurofeedback is a practice in which individuals purportedly learn how to regulate their brainwaves by viewing real-time recordings of their own brain data. A typical neurofeedback session of 20-30 minutes may consist of an individual sitting in a chair, wearing an electrode cap, and playing a video game that s/he controls in real-time with brainwave data, under the guidance of a provider (Hamlin 2018; Hammond 2011; Kamiya 2011; Thibault et al. 2015). The total cost of treatment of up to 40 sessions (Thibault et al. 2015) has been estimated to range from $3,000-10,000 (Ellison 2010; Thibault et al. 2015). EEG neurofeedback is typically marketed for the treatment of both clinical indications—such as anxiety, attention-deficit/hyperactivity disorder (ADHD), and depression (Hammond 2011; Thibault and Raz 2016)—as well as non-clinical indications such as cognitive and performance enhancement (Wexler et al. 2020). According to one major neurofeedback organization, there are likely over 15,000 providers offering neurofeedback globally (ISNR 2017).

Although there are over a thousand studies on neurofeedback, research in this domain has been widely criticized for its lack of rigor, as most studies have lacked double-blinding and sham controls (Arns et al. 2017; Cortese et al. 2016; Schabus et al. 2017; Thibault, Lifshitz, and Raz 2017a; Thibault and Raz 2016). Of the few studies that have utilized doubleblinding and sham controls, results in the neurofeedback group have often been similar to those of the sham group (e.g., Arnold et al. 2013; Logemann et al. 2010; Vollebregt et al. 2014), leading some to argue that the effects of neurofeedback are due to placebo (Arns et al. 2017; Cortese et al. 2016; Schabus et al. 2017; Thibault, Lifshitz, and Raz 2016; Thibault and Raz 2017). EEG neurofeedback, therefore, remains controversial and is not recommended by any professional physician society.

Brain Stimulation Techniques

Transcranial magnetic stimulation (TMS) is a brain stimulation technique where a magnetic field, created by passing an electric current through a coil, is applied to specific areas of the brain (Hallett 2007). TMS was initially approved by the FDA in 2008 to treat major depression and is currently approved to treat migraine headaches and obsessive-compulsive disorder (FDA 2018a). While TMS is being offered as a treatment within traditional health care settings, in a preliminary scoping review, we found that over a hundred clinics promote the technique for off-label (i.e., unapproved) indications ranging from post-traumatic stress disorder (PTSD) to schizophrenia. Additionally, many clinics providing TMS also offer services (such as hyperbaric oxygen chambers, infrared light therapy, and IV nutrient therapy) that are widely considered to be alternative (IOM 2005). For many of the off-label indications advertised—such as ADD/ADHD, autism, and schizophrenia—there appears to be little or conflicting evidence to support the use of TMS (Barahona-Corrêa et al. 2018; Dollfus 2016; Dougall 2015; Oberman, Rotenberg, and Pascual-Leone 2015; Rubio et al. 2016). The total cost of a course of TMS varies but likely ranges between $10,000-$15,000 (Hamblin 2020; Hersh 2013), and uses for off-label indications are not typically covered by insurance.

Another form of brain stimulation, transcranial direct current stimulation (tDCS), is an experimental technique that provides low levels of electrical current to the brain. There are over 2,000 published studies in the scientific literature, claiming that tDCS may be effective for clinical indications, such as chronic pain and depression (Lefaucheur et al. 2017), as well as for cognitive enhancement indications such as improving memory and learning (Buch et al. 2017; Coffman, Clark, and Parasuraman 2014). However, scholars have criticized the proliferation of small sample-size studies, the absence of longitudinal research (see, e.g., Horvath, Forte, and Carter, 2015; Mancuso et al. 2016; Price and Hamilton, 2015), and have questioned whether electrical current is even reaching the brain (Voroslakos et al. 2018). tDCS does not have FDA approval in the U.S., nor is it recommended by any professional organization for the treatment of any indication. In addition to tDCS, a variety of other transcranial electrical stimulation techniques are used by providers, such as cranial electrotherapy stimulation (CES), which is FDA-cleared for anxiety, depression and insomnia; a recent review, however, found that there was limited evidence to support its use for these indications (Shekelle et al. 2018).

ETHICAL ISSUES

As scholars have previously highlighted, the central ethical tension that exists with the provision of CAM is negotiating the balance between patient autonomy and protection from harm (Clark 2000; Ernst and Smith 2018; Gruner 2000; IOM 2005; Sugarman 2003). On the one hand, it can be argued that individuals have the right to choose any therapy, regardless of evidence level. On the other hand, there may be significant ethical concerns for the provision of therapies that lack a strong evidence base. Drawing upon prior literature on the ethics of CAM therapies, as well as prior empirical literature on SPECT diagnostics, EEG neurofeedback, and off-label/experimental uses of brain stimulation, here we highlight the primary ethical concerns regarding the provision of alternative neurotherapies.

Truthful Representation of Evidence Base

Respecting patients' autonomy and their right to make decisions about their medical care is a fundamental principle in medical ethics. However, an autonomous decision to choose an experimental therapy rests upon the notion that patients have truthful and accurate information regarding the evidence base for a given therapy and the alternatives available. In this regard, it is important that the information presented to patients through promotional materials and public representation by clinics (e.g., via their websites), as well as during consultations with health care providers, is accurate and complete. However, in previous work examining the websites of neurofeedback providers, we found that many used misleading claims—for example, advertising for indications for which there was little evidence—and exaggerated the benefits of the treatment (Wexler et al. 2020). One neurofeedback company that operates a chain of "brain performance centers"—and is supported by U.S. Education Secretary Betsy DeVos (Boser 2017; Fink, Eder, and Goldstein 2017)— has been the subject of recent investigations by the National Advertising Division (NARB 2018, 2020) and Truth in Advertising (TINA 2019) for misleading claims (see also FTC 2020).

In addition, both neurofeedback providers and some SPECT clinics often use anecdotes and testimonials to highlight the efficacy of the services offered (Farah and Gillihan 2012; Wexler et al. 2020). Considering that testimonials appearing on providers' websites are inherently biased—they are handpicked by providers, and it is usually impossible to verify their authenticity—they may lead to misinterpretations and create an erroneous impression about the efficacy and evidence base of certain therapies. In addition, in the realm of neurofeedback, many testimonials are not mere attestations to the competence of a provider but rather "miracle cure" assertions regarding what is claimed to be a dramatic, life-changing therapy (Wexler et al. 2020). Furthermore, as other scholars have highlighted, the use of brain imaging and neuroscience images might make alternative neurotherapy services particularly alluring (Chancellor and Chatterjee 2011; Farah 2009; McCabe and Castel 2008). As will be discussed in the next section, issues related to the truthful representation of the evidence base of neurotherapies are particularly pertinent when providers market their services to vulnerable populations.

On an individual level, information about a service is also provided to a potential patient/client directly (e.g., in the office). Although there are no published studies on how alternative neurotherapy providers describe their treatments to their patients/clients, scholars have argued that CAM providers have an obligation to disclose a treatment's evidence base and potential experimental nature (Chancellor and Chatterjee 2011; Gruner 2000; Kaptchuk and Miller 2005; Morreim 2003; Sugarman 2003). This would require going beyond just referring to these therapies as "experimental," since this term may be interpreted in different ways by users (e.g., as anything from "no proven benefit" to "novel but promising"; see Sankar 2004). In this regard, providers should clearly explain whether current scientific evidence supports the use of therapies for specific indications. For example, TMS is not experimental for certain indications, but off-label use for other indications may have differing levels of demonstrated efficacy. Similarly, to date, neurofeedback has demonstrated some efficacy for ADHD (Arnold et al. 2013; Arns, Heinrich, and Strehl 2014), but not for other conditions like bipolar disorder and Tourette's, where its use may be viewed as experimental.

Vulnerable Populations

Alternative neurotherapies are often promoted to individuals who may be considered vulnerable, as they may be more prone than others to be exploited or to suffer psychological harm. For example, many neurofeedback clinics specifically advertise to parents of children with conditions like ADHD, autism, and Asperger's (Wexler et al. 2020) who may consider alternative treatments out of desperation (Horvath et al. 2011). More specifically, in the case of autism, the dearth of efficacious treatments often leads parents to resort to alternative therapies (Hopf, Madren, and Santianni 2016; Shute 2010). Similarly, the use of alternative treatments is not uncommon among parents of children suffering from ADHD (Chan, Rappaport, and Kemper 2003). In this regard, clinics offering alternative neurotherapies may capitalize on parents' desperation by making unfounded claims about the efficacy of their services.

When individuals (or their family members) suffer from a neuropsychological condition, it may affect their autonomous decision-making and render them particularly susceptible to misleading or exaggerated marketing claims. In addition, as has been previously argued, vulnerability may be further exacerbated by the allure of "neuroscientific explanations" (Weisberg et al. 2008), in that individuals may find explanations about conditions more compelling if they involve neuroscience information (Alpert 2012).

Potential Harms

Overall, the risks of physical harms from the above-mentioned alternative neurotherapies are relatively low, although risks vary by type of therapy. For example, in the case of brain stimulation, TMS can lead to short-term side effects such as headaches and neck pain and, in rare cases, seizures (Rossi et al. 2009; Taylor, Galvez, and Loo 2018); tDCS has been shown to occasionally cause skin burns, headaches or dizziness (Antal et al. 2017; Brunoni 2011). SPECT scans provide "small but non-negligible" risks of radiation exposure (Farah and Gillihan 2012; see also Rausch et al. 2016). Because EEG neurofeedback is a noninvasive recording technique, it is unlikely to cause physical harm. In addition, given that both EEG neurofeedback and SPECT neuropsychiatric evaluations may involve making a diagnosis based on brain recordings using methodology that is not recognized by traditional medicine, psychological harms may result from misdiagnosis (e.g., a patient may become distressed after an incorrect diagnosis of depression).

Furthermore, users of alternative neurotherapy services may experience opportunity costs if they choose a non-empirically supported treatment instead of a scientifically validated one. In this context, opportunity cost signifies the loss of potential benefits that a well-established therapy would offer, as well as the loss of time spent seeking or engaging in the form of therapy eventually chosen (Handley and Hollander 2019). (Note, however, that if users do experience benefit—even if from a placebo effect—concerns regarding opportunity costs may be less applicable.) Additionally, given that insurance companies may not cover the costs of alternative neurotherapies, such services may come at a considerable out-of-pocket financial cost. Considering that many alternative neurotherapies described here are promoted for indications for which there is little evidence, financial harms may be particularly concerning. Indeed, from a business ethics perspective, alternative neurotherapies may violate core principles of ethical market transactions, in that there are questions regarding both the efficacy of the services being sold and the claims made about such services (MacDonald and Gavura 2016).

On a societal level, group harms, such as public mistrust in brain technologies or in specific professions, may arise if individuals have negative experiences with alternative neurotherapy services and/or providers. In addition, certain brain technologies may garner a negative reputation if they are used prior to the existence of sufficient evidence of safety and efficacy —which can harm scientists conducting research in these domains, as well as dissuade physicians from utilizing certain approaches if they are proven to be effective (Adinoff and Devous, 2010).

Provider Competency

Alternative neurotherapies involve the use of specialized techniques and devices to treat clinical indications. In this regard, providers should have appropriate competency to offer these therapies and address the clinical needs of their patients. Both relevant professional/educational background, as well as appropriate training for the specific services offered, may be required in order to ensure that providers have the skills and knowledge needed to deliver these therapies in a safe and effective manner. In the field of neurofeedback, however, in previous research we found that the majority of providers in our sample offering therapies for clinical indications did not have doctoral-level degrees in medicine or psychology (Wexler et al. 2020). Furthermore, while having a medical degree (MD) may establish baseline competency, it is unclear whether such a degree is sufficient if providers lack a specialization that is relevant to the treatments offered. For example, it not clear that an MD specializing in oncology possesses the competency to use alternative neurotherapies to treat patients suffering from PTSD or autism.

Training in the specific techniques being offered is equally important. Currently there are a number of specialized training courses for SPECT and transcranial electrical/magnetic stimulation that offer continuing medical education credits. However, these courses prepare trainees for conventional and/or research uses of SPECT and transcranial electrical/magnetic stimulation, rather than its utilization for unconventional indications. In the case of neurofeedback, training may vary widely. Many providers possess a “board certified in neurofeedback” (BCN) certification (Wexler et al. 2020) that is offered by the Biofeedback Certification International Alliance (BCIA), which requires 25 hours of mentoring and 100 neurofeedback sessions, yet devotes only 2 of the 36 hours of didactic education to the “research evidence base for neurofeedback” (BCIA 2004, 2019). Furthermore, given that the BCN certification is open to those with bachelor’s degrees in fields such as speech pathology and sports medicine, it is unclear whether neurofeedback providers have the minimum competency to provide therapies for many of the promoted clinical indications.

Conflicts of Interest

A particularly pertinent ethical issue concerning alternative neurotherapies is the potential conflict of interest in research aiming to establish the efficacy of such therapies. Indeed, many studies supporting the efficacy of alternative neurotherapies have been conducted by providers of these techniques. With regard to neurofeedback, scholars have raised concerns about bias, given that those who publish research—as well as those actively involved in neurofeedback societies—often have financial interests, either via private practice or connections to vendors of neurofeedback equipment (Thibault, Lifshitz, and Raz 2017b; Thibault and Raz 2017). With regard to SPECT, many of the publications supporting its utility for psychiatric evaluation have been conducted by those who have a financial stake in the research outcome (see, e.g., Amen, Hanks, and Prunella 2008; Amen et al. 2011; 2012; 2015; Amen and Carmichael 1997; Henderson et al. 2020; Raji et al. 2014). Although concerns regarding potential conflict of interest are not uncommon in biomedical sciences more broadly (Dunn et al. 2016; Johnston 2008), the commercial interests and lack of independent research in these two domains are particularly notable.

LEGAL ISSUES

Although the legal issues surrounding the *sale* of neurotechnology devices in the U.S. have been the subject of much discussion in the neuroethics literature (Dasgupta 2020; Jwa 2019; Wexler 2015; Wexler and Reiner 2019; Wexler and Thibault 2019; Zettler 2016), the *use* of such devices in clinical settings presents a distinct set of legal considerations. Because the FDA does not govern the practice of medicine (FDA 2018b), the regulation of neurotherapy services for medical treatment largely falls to individual states, which define and limit who (i.e., individuals with which types of licensing) can offer medical services for which indications (Cohen 1998). Licenses—such as those for physicians, registered nurses, and dentists—are typically obtained after providing evidence of education and training; some require proof of passing written and/or clinical exams (Eisenberg et al. 2002). Licenses allow individuals to provide a specific set of services that are considered to be within the limits of one's field, or "scope of practice" (Cohen 2002).

When considering the regulatory concerns related to alternative neurotherapies, the primary questions related to licensing and scope of practice are twofold. First, does the provider hold a professional license; second, is the technique and indication treated by the provider considered to be within the scope of practice for that license (Cohen 1998; Striefel 2009). Additionally, since some states have specific provisions regarding the use of unconventional or CAM treatments, a third question arises with regard to whether a provider has complied with that state's legal requirements involving such therapies. In what follows, we discuss how these three questions play out in the context of SPECT neuropsychiatric evaluations, EEG neurofeedback, and off-label/experimental uses of brain stimulation.

With regard to licensing, based on our informal scoping review of clinics offering SPECT neuropsychiatric evaluations and those promoting TMS for off-label indications, it appears that most individuals offering such services have MDs and are presumably licensed to practice medicine. In the realm of neurofeedback, however, there appears to be far more variability in terms of licensing. One survey of those who hold biofeedback and neurofeedback certifications found that 18% were unlicensed (Neblett, Shaffer, and Crawford 2008). Furthermore, in prior empirical work examining neurofeedback clinics in the U.S., we found that only a fraction of practitioners (3.9%) held MDs; many (32.1%) held PhDs in psychology, and the remainder reported being licensed mental health counselors, licensed social workers, or did not provide any information about a degree or license in their directory listings (Wexler et al. 2020). Additionally, given that some licensed neurofeedback providers have publicly expressed concern at the number of unlicensed providers practicing neurofeedback (Hammond and Kirk 2008), it appears that lack of licensing may be a relevant regulatory issue in the realm of EEG neurofeedback.

The second, related question is whether licensed providers are indeed offering services within their scope-of-practice. Since providers with MDs have broad leeway to practice medicine for a wide variety of indications (Cohen 2002), there are unlikely to be significant scope-of-practice issues in the realm of SPECT neuropsychiatric evaluations and off-label TMS, although ethical questions surrounding competency (see above discussion) and state-level provisions regarding unconventional treatments (see below) would still be applicable.

However, with regard to neurofeedback, the question of whether psychologists, mental health counselors, social workers, and others are operating within their scope of practice by providing neurofeedback is largely dependent both on state-level definitions, as well as the specific clinical indications being treated.

To delve further into scope-of-practice issues with regard to non-MD neurofeedback providers, we examined state-level regulations for the top three licenses (psychologists, mental health counselors, and social workers) in the three states with the largest number of neurofeedback providers in our prior sample (California, Texas, and Florida; see Wexler et al. 2020). Although scope-of-practice specifications varied considerably (California Business and Professions Code 2019a, 2019b, 2019c; Florida Statutes 2019a, 2019b; Texas Statutes 2019a; 2019b; 2019c), overall they encompassed a wide array of psychological, mental health, and behavioral health practices. Thus, it appears that licensed psychologists, mental health counselors, and social workers who provide neurofeedback services to treat psychological or mental health indications would be operating within their scope of practice (see also discussion in Striefel 2000). However, given that we found that many neurofeedback providers in our prior sample claimed to treat other indications—such as neurological issues (e.g., traumatic brain injury, stroke, epilepsy), autism, and pain (see Wexler et al. 2020)—it appears likely that at least some providers may be operating outside their scope-of-practice. Indeed, there have been several reports of investigations of neurofeedback providers by state medical boards (Cleveland 19 News 2005; Leys 2015; Stokes 2007).

The third main regulatory question centers on the legal obligations of practitioners when utilizing unconventional or CAM treatments. Indeed, many states have regulations specifying requirements for the provision of such treatments, such as mandating patient assessment and specific informational disclosures. In Texas (TX), for example, any physician providing CAM must perform a thorough assessment of the patient (Texas Administrative Code 2016); California (CA) and Florida (FL) do not have analogous requirements (California Business and Professions Code 2018; Florida Statutes 2018). All three states, however, require some form of informational disclosure to the patient regarding the nature of the treatment. Some require disclosure of the provider's credentials (CA & FL); the theory or mechanism of action of the treatment (CA & TX); the risk and benefits of treatment (FL & TX); and regulatory status of the therapy (TX).

Finally, while scope of practice and CAM provisions are primary regulatory concerns, other legal issues also come into play with regard to the provision of alternative neurotherapies. For example, just as in conventional medicine, dissatisfied patients or clients may bring a malpractice case against a provider if they feel they have been harmed (Cohen 1998; Cohen and Eisenberg 2002). In such an instance, legal considerations would center on whether a practitioner has provided standard-of-care treatment. Yet assessments of what is considered standard of care are complex in the context of CAM, as by definition CAM departs from the norms of accepted biomedical treatment (Cohen and Eisenberg 2002; Doyle 2001; Gilmour et al. 2011; Raposo 2019). Some scholars have therefore suggested methods of assessing standard of care in CAM that are based on available evidence regarding safety and efficacy

(Cohen and Eisenberg 2002). Notably, however, there is little prior case law to draw upon regarding malpractice cases against CAM providers (Cohen 1998).

CONCLUSION

This article has outlined the unique characteristics of alternative neurotherapies and the distinct ethical and legal questions that arise from their provision. By drawing attention to alternative neurotherapy practices as a whole, rather than discussing them singularly, we have attempted to recognize and draw attention to a larger social phenomenon that merits ethical scrutiny. Furthermore, linking this phenomenon to CAM allows us to take advantage of a wide body of ethical and legal scholarship in this domain.

One potential explanation for the rise in alternative neurotherapies, particularly in recent decades, can be found by examining how regulation in the U.S. applies differentially to medical devices and pharmaceutical drugs. While the prescription of drugs is tightly regulated at the state level—for example, medical doctors can prescribe drugs, but psychologists, social workers, and naturopaths typically cannot (Cohen 2002)—there are no analogous restrictions surrounding the use of medical devices (Wexler 2020). This regulatory difference has likely contributed, at least in part, to the flourishing of alternative neurotherapies.

Moving forward, future research should assess the efficacy of alternative neurotherapies, as well as examine attitudes of stakeholders involved in both providing and receiving alternative neurotherapies (see, e.g., Anderson, Mizgalewicz, and Illes 2013). Exploring the perspectives of relevant stakeholders may offer a better understanding of the context within which these therapies are offered, as well the saliency of specific ethical concerns. If, for example, users of alternative neurotherapies widely report symptom improvement and overall satisfaction (especially if they have tried conventional therapies unsuccessfully), then concerns about financial and opportunity costs may be less relevant—and policy recommendations could focus on issues such as truthful representation, adequate provider training, and minimization of conflicts of interest. Therefore, additional research in this domain should aim to gather empirical data that can help inform policy recommendations to encourage the ethical provision of alternative neurotherapies.

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