Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies

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The wearable neurotechnology market targets consumers with promises of cognitive benefit and personal wellness. Scientific evidence is essential to substantiate claims about utility, safety, and efficacy and for informed choice and public trust.

Technologies that read signals from or stimulate the brain have historically been accessible to only researchers and clinicians. Now, however, they are being sold directly to consumers (DTC) and adapted for use by the general public. Among their many applications, these devices are purported to improve cognitive functions such as memory and attention, optimize brain fitness, and control games and objects, including those that may enhance autonomy among people with injuries of the brain and spinal cord.

Ethics discourse around DTC health-related tests and products is not new; ethicists have seen it for CT imaging marketed to the healthy wealthy (Illes et al., 2003) and for genetic testing (Hogarth et al., 2008; Caulfield and McGuire, 2012; Gollust et al., 2017; Singleton et al., 2012), among others. Despite this history, the tremendous projected growth of the DTC neuro-related industry, and calls for better engagement around responsible innovation (Wexler and Thibault, 2018; Wexler and Reiner 2019; Wurzman et al., 2016), empirically driven knowledge about the ethical realities of commercializing these devices in the open marketplace is limited. We were interested in further closing this gap by focusing an ethics lens on the marketing claims made about both recording and stimulating wearable neurotechnology.

Strategic Approach

To identify websites offering wearable neurodevices and claims about them, we conducted extensive searches (Google.com, Yahoo!, and AltaVista) using key words such as neurodevices (any wearable device that directly performs its function by interacting with, recording from, or manipulating the central nervous system) and direct-to-consumer (available for purchase on the open marketplace without physician involvement or a license for use). We included all those available for purchase either through online retailers (i.e., Amazon), crowdfunding sites such as Kickstarter and Indigogo, and manufacturer websites or available for purchase in stores.

We used conventional qualitative methods to develop an initial code book using descriptive content analysis and identified 26 major domains of coding *a priori* for type of device, explicitly (text) and implicitly (image) targeted consumer groups, and explicit (verbatim) and implicit (image-based) claims. Authors C.L. and N.M. individually identified the verbatim claims for a 20% subset of the sample for reproducibility and then jointly generated the final code book and performed the analysis. Main webpages, as well as subpages with links accessible from the homepage, were included. Hyperlinks that led to a website with a root website address different from the official device website were not. A charting method enabled the creation and management of database of devices and related claims for thematic coding. The results are based on website content at the time of analysis and writing.

Observations and Findings

What Are the Claims?

We identified 41 DTC wearable neurodevices available for purchase. Of these, 22 were recording devices (e.g., electroencephalogram [EEG]) and 19 were stimulating devices (e.g., transcranial direct current stimulation [tDCS]). We found 20 unique claims for the neurodevices (171 total claims across the 41 devices in the sample) (Table 1) that we clustered into four main categories: wellness, enhancement, practical applications, and health. We note that themes such as enhancement, wellness, and health represent a conceptual continuum with blurred boundaries, and we relied therefore on the verbatim claims about them – for example, enhancement as augmented performance beyond the user's standard level of functioning. In order to be considered a health claim the manufacturers had to refer to a named medical condition.

Claims about wellness were made for 31 of the devices, enhancement for 28, and health for 9, including conditions such as amyotrophic lateral sclerosis (ALS) and other neurodegenerative disorders, depression, chronic pain, insomnia, attention-deficit/hyperactivity disorder (ADHD), and post-traumatic stress disorder (PTSD). For one device, the claim pertained to the slowing of cognitive decline. In addition to symptom improvement, some claims also suggested improved autonomy for individuals with cognitive and motor disabilities. Food and Drug Administration (FDA) approval was cited for only one device, which was promoted for depression, anxiety, and insomnia. Claims of practical utility were made for four EEG-controlled devices that could move a target around, two for creative art, seven for research, and one to promote safety by detecting fatigue.

To Whom Are These Claims Targeted?

Mostly the general public. However, we could identify 1 or more of 11 specific consumer groups for 32 of the 41 devices: older adults, athletes/trainers, children, researchers, health care providers/professionals, people with medical conditions, employees/employers, students, marketers, musicians, and gamers.

Table 1. Claims by Category

Category	Claim	Frequency	Percent of total	Example
Wellness	Relieve stress/anxiety	17	10%	"myBrain Technologies built a new drug-free, easy-to-use, and perfectly safe solution to stress" (MyBrain Technologies MeloMind)
	Improve sleep quality	17	10%	"Because the Sleep Shepherd lets you directly control your brain rate, you can naturally build a better, healthier sleep cycle that allows you to fall asleep faster, stay asleep longer, and have more energy during the day" (Sleep Shepherd Blue)
	Improve general wellness	16	9%	"Versus provides a path to wellness through brain exercises" (Versus)
	Augment meditation/ relaxation	11	6%	"Muse: the brain sensing headband will elevate your meditation experience. It gently guides your meditation through changing sounds of weather based on the real-time state of your brain" (InteraXon Muse)
	Increase self-awareness	9	5%	"Introducing Lowdown Focus Brain Sensing Eyewear™ with the Smith Focus App to help you develop a heightened sense of self-awareness" (Smith LowDown Focus)
	Improve mood	4	2%	"If you want to improve your mood… Omni is for you" (Omni)
	Lose weight	1	0.6%	"Modius uses neuro-technology to make weight loss easier by reducing your appetite and cravings" (Modius)
Enhancement	Assist with self-regulation/ neurofeedback	19	11%	"The FocusBand headset and app provides neurofeedback, a proven method to train the brain" (FocusBand)
	Increase concentration/ focus	15	9%	"The drug free way to learn to focus" (Narbis)
	Improve general cognition	13	8%	"A smart headset helps you to achieve peak mental fitness" (Brainlink)
	Increase efficiency/ productivity	9	5%	"Mindset can give suggestions on how to improve your productivity: schedule emails during your downtime, and save your best hours for your deep work sessions" (Mindset)
	Support learning/training	7	4%	"Halo Sport accelerates how fast people learn skills like golf, piano, triathlon, clarinet, and CrossFit" (Halo Sport)
	Boost physical performance	5	3%	"Enhance your mental/physical performance with photobiomodulation" (Vielight)
	Enhance Memory	5	3%	"Enhance your memory, logic and other cognitive skills" (Neeuro's Senzeband)
Practical Applications	Perform research	7	4%	"NeuroDEV offers neurotechnology that extends beyond hospitals and research facilities, giving developers and professionals the opportunity to access affordable brainwave technology and integrate it with their own applications for the purpose of research, monitoring brain waves and improving brain health" (Vielight Neuro Alpha)
	Control technology	4	2%	"Control machines with the power of your mind and make science fiction a reality today" (Emotiv)
	Create art	2	1%	"Whether commanding drones or wheelchairs, creating music or art, or adapting digital experiences to real time emotions, the interface between the brain and computer has never been easier" (Emotiv Insight)
	Promote safety	1	0.6%	"Our wearable technology prevents microsleeps by providing accurate alertness measurements in real-time to operators and drivers so they can take charge when it comes to safety" (SmartCap Technologies)
Health	Improve a medical condition	5	3%	"Some conditions where Bellabee has been used include: Anxiety problems, Sleep disorders, Stress-related issues, Concentration problems, ADD and ADHD issues (attention deficit disorders), PTSD (post-traumatic stress disorder)" (Bellabee)
	Promote autonomy after disability	4	2%	"The proof of concept software connects a wearable display with an EMOTIV Insight Brainware headset to show how a person with severe mobility restrictions, such as amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases, could regain more independence" (Emotiv Insight)
Total		171	100	

Are the Claims Supported by Evidence?

We identified a link to research or a resource to support associated claims for 33 of the 41 devices, but we only found a link to one or more relevant peer-reviewed research papers for 8 of the device claims overall. Of the remainder, 29 had links to citations to general science research and scientific concepts. For example, one website discussed how tDCS may, in general, improve cognitive functioning but did not explicitly say their device did so. Other links were to user testimonials, gray literature, company/in-house research, or peer-reviewed literature that was irrelevant to the device or claim at hand.

Are Claims of Benefit Accompanied by Equally Accessible Warnings of Risk?

Largely not. Risks and warnings associated with the devices were neither stated on company websites nor discernable without purchase in more than half of the sample (21/41). Websites that did have risk and warning statements referenced a wide range of potential side effects: topical discomfort, redness, skin irritation, overheating, tiredness, headaches, dry throat, dizziness, tingling, burns, pain, changes in sleep or energy, heightened emotionality, and nausea.

When safety profiles were outlined, they took the form of suggestions and directions for use, such as not to use tDCS on pregnant women, children, and others with implanted medical devices, only running tDCS stimulation at intensity levels that are not uncomfortable, and to disconnect the device if the sensors feel hot during charging or use. Few companies explicitly claimed that their device was safe with statements such as "The headset safely measures brainwave signals and monitors the attention levels" (NeuroSky MindWave).

We recognize that first-line and expanded safety information may come with a device once purchased. We note that two companies did make user materials available without purchase, but neither provided consumers with any safety profiles or guidelines for safe use.

Neuroethical Considerations

The claims that producers make about brain wearables and strategies for communicating them are of central interest to neuroethics as they touch upon core issues of transparency, rights, and responsibility. In our view, two sets of core ethical concerns posed by the DTC wearable neurotechnology market arise from the present analysis: (1) concerns about unsubstantiated claims and (2) unease about substantiated claims.

Unsubstantiated Claims

Good business ethics in biomedicine—neuroscience or otherwise—requires stringent in-house research that validates company claims about their devices, grounds honest marketing practices, and ensures adherence to robust regulatory oversight (Bubela and McCabe, 2013). Unsubstantiated claims and ethically questionable strategies may arise when a claim is based generally on the performance of a given technology over that of a specific device. For example, one company website states, "tDCS or Transcranial Direct Current Stimulation is an incredibly promising, noninvasive way of improving brain function." What is missing, to our knowledge, however, is that the specific tDCS device itself has not actually been proven to do so. This is a particularly salient consideration given how these devices vary widely in terms of the number and placement of electrodes used and the fact that DTC devices will be used in naturalistic settings rather than a controlled laboratory environment.

While the US Federal Trade Commission (FTC) has begun cracking down on brain-training computer programs or applications that claim enhancement or improvement in cognitive functioning (Robbins, 2016), at the time of this writing we are unaware of any complaints brought against a neurowearable company making the same claims. Public trust is at risk when a product purported to be based on science is not. Moreover, patients' lives are at risk if conventional medical interventions are circumvented in favor of unproven benefits of neurowearables. Ordinarily, medical devices fall under FDA regulatory purview based on the health claims made about them rather than about their mechanism of action. It is unclear then how eight DTC devices that claim medical benefit appear to have escaped the requirement to provide FDA confirmation of the safety and efficacy of their stated function.

In addition to the neurodevices for which health claims are made without proof of FDA approval, many others evade regulatory control by referencing disease but not articulating that the device can ameliorate that condition. For example, a tDCS company claims "Our non-invasive, bioelectronic platform effectively targets autonomic nerve pathways important in a number of disease processes while providing superior safety relative to pharmaceutical interventions." While the company mentions that the device aims to influence nerve pathways that are important in disease processes, they stop at the point of directly saying that their product alters disease course. Nonetheless, this could be interpreted as a legitimate health claim, leading to uninformed medical decisions. In our view, relevant current regulation is either lacking or insufficiently enforced.

Finally, some devices may avoid regulatory scrutiny with claims about wellness and enhancement rather than health, e.g., "...giving your clients access to the latest technological innovations, taken out of neuroscientific research laboratories to deeply improve their wellbeing" and "...a path to wellness through brain exercises." While there is no suggestion that a user should supplant use of this device over a conventional therapeutic for a brain or mental health conditions, there is also no warning to not do so.

Substantiated Claims

Potential harms remain even if these devices perform as advertised, not the least of which involve safety (Wurzman et al., 2016). If, in fact, DTC tDCS devices can improve cognition, then surely that is a benefit people will seek as they have historically over time. However, DTC devices are, by definition, unsupervised, and there is little to stop a user from wearing a device continuously with unknown effects on neuroplasticity. Many of the tDCS devices allow the wearer to control the level of stimulation delivered. It is not unreasonable to imagine that many users will equate longer and more intense stimulation with increased improvement and effect. There is very little research on the long-term impact of tDCS use, especially when that use is long term and frequent. This is a particular concern given our findings of absent risks and warnings information and protocols for safe use and possible interactional or adverse effects of exchanging a known, effective intervention for a condition with the use of a device. Furthermore,

while claims about supported autonomy after serious disability involving the brain or spinal cord might eventually be borne out, it is likely that the extent of such improvement would be limited. As such, the technology should not be expected to supplant human interaction or aid, and claims should not be interpreted as a justification for reduction or redirection of resources.

Concluding Thoughts

Scientific evidence is essential to legitimize claims about utility, safety, and efficacy and for informed choice and public trust. Continued vigilance to the claims landscape for brain technologies is especially important as this market captures the imagination of a neuro-obsessed world. It is vital that regulation and oversight of neurodevices keep apace with, or at least remains relevant to, the evolution of the fast-paced neurotechnology landscape in order to ensure that the benefits of this market are realized, harms avoided, and good practices motivate industry to own the ethics of their innovation.

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REFERENCES

Bubela, T., and McCabe, C. (2013). Value-engineered translation for regenerative medicine: meeting the needs of health systems. Stem Cells Dev. *22* (*Suppl 1*), 89–93.

Caulfield, T., and McGuire, A.L. (2012). Direct-to-consumer genetic testing: perceptions, problems, and policy responses. Annu. Rev. Med. *63*, 23–33.

Gollust, S.E., Gray, S.W., Carere, D.A., Koenig, B.A., Lehmann, L.S., McGUIRE, A.L., Sharp, R.R., Spector-Bagdady, K., Wang, N.A., Green, R.C., and Roberts, J.S.; PGen Study Group (2017). Consumer perspectives on access to direct-to-consumer genetic testing: role of demographic factors and the testing experience. Milbank Q. *95*, 291–318.

Hogarth, S., Javitt, G., and Melzer, D. (2008). The current landscape for direct-to-consumer genetic testing: legal, ethical, and policy issues. Annu. Rev. Genomics Hum. Genet. *9*, 161–182.

Illes, J., Fan, E., Koenig, B.A., Raffin, T.A., Kann, D., and Atlas, S.W. (2003). Self-referred whole-body CT imaging: current implications for health care consumers. Radiology *228*, 346–351.

Robbins, R. (2016). U.S. Cracking Down on "Brain Training" Games. https://www.scientificamerican.com/article/u-s-cracking-down-on-brain-training-games/.

Singleton, A., Erby, L.H., Foisie, K.V., and Kaphingst, K.A. (2012). Informed choice in direct-to-consumer genetic testing (DTCGT) websites: a content analysis of benefits, risks, and limitations. J. Genet. Couns. *21*, 433–439.

Wexler, A., and Reiner, P.B. (2019). Oversight of direct-to-consumer neurotechnologies. Science *363*, 234–235.

Wexler, A., and Thibault, R. (2018). Mind-reading or misleading? Assessing direct-to-consumer electroencephalography (EEG) devices marketed for wellness and their ethical and regulatory implications. J. Cogn. Enhanc. *3*, 131–137.

Wurzman, R., Hamilton, R.H., Pascual-Leone, A., and Fox, M.D. (2016). An open letter concerning do-it-yourself users of transcranial direct current stimulation. Ann. Neurol. *80*, 1–4.