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Minding the ‘gaps’ in the federal regulation of transcranial direct current stimulation devices

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INTRODUCTION

What if people could enhance their cognitive abilities by simply applying small amounts of electricity to their brains? The prospect is certainly tantalizing, but was previously only the stuff of movies and books rather than a reality. Now, however, producers of a new breed of devices marketed with taglines such as ‘power your mind’ and ‘unlock your brain’s true potential’ are seeking to bring a real life slice of science fiction to consumers.¹

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¹ Anna Wexler, *A Pragmatic Analysis of the Regulation of Consumer Transcranial Direct Current Stimulation (tDCS) Devices in the United States*, 2 J. L. & Biosci. 669, 680 (2015). Cf. Dan Hurley, *Jumper Cables for the Mind*, Nov. 1, 2013, http://www.nytimes.com/2013/11/03/magazine/jumper-cables-for-the-mind.html?pagewanted=all&_r=0 (last accessed Apr. 12, 2016) (‘[I]f the science continues to show that a little zap can safely boost our brainpower, surely some people will find it hard to resist.’).

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The apparatuses at issue are transcranial direct current stimulation (tDCS) devices 'that utilize[] low amplitude direct current to modulate brain excitability, facilitating or inhibiting spontaneous neuronal activity'.² The possible medical applications of these devices have been extensively studied, as have possible cognitive enhancement effects.³ But all of this research has been undertaken by experts in controlled environments, and thus far, 'tDCS is not approved in the United States by the Food and Drug Administration (FDA) as a medical treatment for any indication'.⁴ As such, researchers may only employ tDCS devices in experimental settings and are highly constrained in their ability to procure them.⁵

But the average consumer faces no such restrictions in terms of her ability to purchase and use these devices.⁶ And although meaningful risks associated with the use of tDCS devices have yet to be revealed,⁷ many believe that the nascent nature of this technology and its applications coupled with the complexity and relatively uncharted state of the brain makes discovery of such risks a distinct possibility.⁸ Accordingly, a body of literature has developed that argues that the broad and relatively uninhibited public availability and use of tDCS devices is troubling, and criticizes perceived regulatory deficiencies that have allowed this situation to develop.⁹

² Marta Parazzini et al., *Effect of the Interindividual Variability on Computational Modeling of Transcranial Direct Current Stimulation*, 2015 COMPUTATIONAL INTELLIGENCE & NEUROSCI. 1, 1 (2015).

³ Eg Roi Cohen Kadosh (ed.) *THE STIMULATED BRAIN: COGNITIVE ENHANCEMENT USING NON-INVASIVE BRAIN STIMULATION* 181–454 (2014) (Broadly presenting research into the therapeutic benefits and cognitive enhancement effects of tDCS).

⁴ Wexler, *supra* note 1, at 671. See also Marom Bikson, Sven Bestmann & Dylan Edwards, *Neuroscience: Transcranial Devices are not Playthings*, 501 NATURE 167, 167 (2013) ('Patients receiving tDCS do so in a controlled environment, under guidance from institutional ethics review boards and with strict criteria for patient inclusion.').

⁵ Wexler, *supra* note 1, at 671.

⁶ *Id.*; Hannah Maslen et al., *Regulation of Devices for Cognitive Enhancement*, 382 LANCET 938, 938 (2013) ('[L]aypeople can easily access [brain stimulation] devices, without regulation or oversight.').

⁷ Eg F. Fregni et al., *Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): Review and Recommendations From an Expert Panel*, 32 CLIN. RES. & REG. AFF. 22 (2015) (Reviewing a breadth of studies utilizing tDCS devices and finding that 'the side-effects of tDCS are mild, benign, and short-lived'); Andre Russowsky Brunoni et al., *A Systematic Review on Reporting and Assessment of Adverse Effects Associated with Transcranial Direct Current Stimulation*, 14 INT'L J. NEUROPSYCHOPHARMACOLOGY 1133 (2011) (Finding the instance and severity of reported adverse effects of tDCS device use in studies to be minimal). But see Kate Riggall et al., *Researchers' Perspectives on Scientific and Ethical Issues With Transcranial Direct Current Stimulation: An International Survey*, NATURE: SCIENTIFIC REPORTS 6 (2015), <http://www.nature.com/articles/srep10618> (last accessed Apr. 12, 2016) (Finding that tDCS researchers are greatly concerned by a general lack of research into the practice's adverse effects).

⁸ Eg Nicholas S. Fitz & Peter B. Reiner, *The Challenge of Crafting Policy for Do-it-Yourself Brain Stimulation*, 41 J. MED. ETHICS 410, 410 (2015) (Lamenting that, all too often, 'authors give only passing reference to the concerns that might arise with [tDCS device] misuse'); Hannah Maslen et al., *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, 1 J. L. & BIOSCI. 68, 70–72 (2014) (Outlining concerns that significant harms from tDCS device could manifest themselves in multiple ways, including: misuse of the technology, interaction with medical or other substances, material neural changes in developing brains, or long-term side-effects.); Veljko Dubljević, Victoria Saigle & Eric Racine, *The Rising Tide of tDCS in the Media and Academic Literature*, 82 NEURON 731, 733 (2014) (Noting the lack of research into the potential detrimental effects of tDCS device use.).

⁹ Eg Fitz & Reiner, *supra* note 8, at 411 (Finding it troubling that '[i]n the USA and the European Union, devices marketed for tDCS are not covered by the existing regulatory framework'); Maslen et al., *supra* note 8, at 69 (Expressing strong concern 'that these potentially risky devices are being bought and used by individuals with little knowledge and training, and in the absence of rigorous regulatory safeguards.').; Dubljević et al., *supra* note 8, at 736 (Criticizing the fact 'that tDCS is readily available as a service, product, or even a homemade device').

Yet to effectively assess the adequacy of the regulations governing a type of device, one must have a firm understanding of the laws applicable to it in any given circumstance. In this vein, Anna Wexler has written an excellent overview and analysis of the federal regulatory environment that applies to tDCS devices in the USA.¹⁰ She shows that there is no general regulatory gap when it comes to these products. In situations where specific medical device regulations do not apply to them, general products rules do. There is no circumstance in which tDCS devices are not regulated in some manner. Thus, criticisms that call for more regulation without meaningfully engaging the full expanse of existing law undermine their own relevance.¹¹

In this article, we expound on Wexler's findings in two important ways. First, we highlight one of the key consequences of a product being categorized as a medical device: that it must clinically prove its medical effectiveness in addition to the risks associated with its use. This places a significant additional burden on producers; one that is not necessarily appropriate when a product is destined for general consumers rather than patients, particularly, when no substantial risks are proven to result from its use. Second, we address the body of scholarship that, rather than asserting the existence of a general regulatory gap when it comes to tDCS devices, argues that there are gaps within general products and medical device regulations specifically. We counter such contentions on two fronts. We note that the lack of a proof of effectiveness requirement under general products regulations is not a gap because, as asserted in the previous section, its absence is not inherently improper for products marketed to ordinary consumers as opposed to patients. For the same reason, the alleged inapplicability of medical device regulations to these tDCS devices is similarly not a regulatory gap. We next illustrate that medical device regulations are not necessarily inapplicable to tDCS devices destined for the general market. Instead, given the broad discretion the FDA has in categorizing something as a medical device, the application of these rules is likely simply a matter of government enforcement.

Overall, we supplement Wexler's work and call for further discretion and more comprehensive legal analysis from those who argue that additional federal regulation is needed for tDCS devices.¹²

CONSIDERATIONS OF DEVICE EFFECTIVENESS

With regard to applicable regulatory frameworks, tDCS devices potentially fall into one of two broad categories: medical devices or general consumer products.¹³ The former, in relevant part, makes stringent demands upon those seeking to market their products as

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory, which is

¹⁰ Wexler, *supra* note 1.

¹¹ *Id.* at 672 ('[B]efore calling for additional regulation or concluding that there is a 'regulatory gap', it must first be determined that the problem is the lack of regulation.').

¹² *Id.* at 696 ('Rather than adopting an alarmist approach to the new reality of consumer brain stimulation, we must navigate this unfamiliar terrain with practical, grounded assessments of social and regulatory issues.').

¹³ See *id.* at 673 (Dividing the regulatory frameworks applicable to tDCS devices into those covering 'medical' and 'consumer' products).

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals.¹⁴

The applicability of this definition to tDCS devices is analyzed in the next section. Of relevance here is the fact that, once classified as a medical device, a product must clinically demonstrate its safety *and* effectiveness for medical diagnosis or treatment before it can be offered to patients.¹⁵ A balance must therefore be struck between these two characteristics, with stricter testing and oversight required of those devices exposing users to higher levels of risk.

User safety is rightly a foremost concern when marketing devices to patients, who, as consumers, inhabit a highly vulnerable position: they are suffering from an affliction that necessitates their consumption of a therapeutic good, but lack the personal knowledge to make informed choices in this regard and are almost completely reliant upon the information and advice provided by medical professionals and medical device marketers.¹⁶

But user safety considerations are not exclusive to medical device regulation. Though not as stringent, there is very compelling law with regard to the safety of devices intended for general consumers, and the open presentation of any potential harms attendant with their use.

First, various government agencies have Congressional mandates to ensure the safety of general products. The Federal Trade Commission can take action against 'unfair or deceptive acts or practices in or affecting commerce';¹⁷ a power it has employed liberally to regulate 'sales of hazardous or systematically defective products or services without adequate disclosures'.¹⁸ In addition, the Consumer Product Safety Commission has the following purposes:

- (1) to protect the public against unreasonable risks of injury associated with consumer products;

¹⁴ 21 U.S.C. § 321(h) (2009).

¹⁵ 21 U.S.C. § 360c(a) (2012) (Classifying medical devices based on their safety and effectiveness). See also Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1753 (1996) ('Before a new therapeutic drug or medical device can be commercialized in the United States, it must meet the safety and effectiveness requirements of the [FDA].').

¹⁶ Eg Steven Joffe & Robert D. Truong, *Consent to Medical Care: The Importance of Fiduciary Context*, in *THE ETHICS OF CONSENT: THEORY AND PRACTICE* 347, 351 (Franklin G. Miller & Alan Wertheimer eds. 2010) (Explaining the inherently vulnerable position of medical patients as consumers of therapeutic products); ALAN WERTHEIMER, *COERCION* 62 (1987) ('[P]atients may have limited ability to understand the precise nature of the available options or weigh rationally the risks and benefits of the alternatives.');

Nancy M.P. King, *The Line Between Clinical Innovation and Human Experimentation*, 32 SETON HALL L. REV. 573, 574 (2002) ('All sick patients are a vulnerable population to at least some degree.').

¹⁷ 15 U.S.C. § 45(a) (2006).

¹⁸ FED. TRADE COMM'N, *FTC POLICY STATEMENT ON DECEPTION 1* (1983), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf (last accessed Apr. 12, 2016).

- (2) to assist consumers in evaluating the comparative safety of consumer products;
- (3) to develop uniform safety standards for consumer products and to minimize conflicting State and local regulations; and
- (4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.¹⁹

Second, products liability law serves to hold producers accountable for the harm their products reap. Particularly, it

operates largely on products that have observable utility and hidden risks, relative to the safer alternatives available on the market. The observable-utility feature offers an advantage that attracts consumers. The hidden-risk feature leads to injuries. This combination of features is unlikely to be regulated well by the market. The market is likely to fail, for these products, in providing incentives for optimal consumption or for producers to make welfare-enhancing design changes. In contrast, for products with open and obvious risks, the market is likely to regulate optimally, in the sense that where alternative designs exist that offer equivalent utility and less risk, the market will effectively exclude the riskier products.²⁰

This body of law therefore encourages the disclosure of risk, and the divulgement of and seeking of accountability for hidden risk through legal actions addressing harm suffered.²¹

Finally, where the risk accompanying a widely used product is sufficiently proven and severe, Congress has taken action to mandate specifications and warnings necessary for its manufacture and marketing.²²

Thus, as opposed to its focus on safety, what is more unique to the regulation of medical devices, compared to that of general products, is a commensurate focus on effectiveness.²³ While the classification of an apparatus once it is labeled a medical

¹⁹ 15 U.S.C. § 2051. See also About CPSC, CONSUMER PRODUCT SAFETY COMMISSION, <http://www.cpsc.gov/en/About-CPSC/> (accessed Mar. 17, 2016) ('CPSC is charged with protecting the public from unreasonable risks of injury or death associated with the use of thousands of types of consumer products under the agency's jurisdiction.').

²⁰ Keith N. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457, 2458 (2013). See also Gary T. Schwartz, *New Products, Old Products, Evolving Law, Retroactive Law*, 58 N.Y.U. L. REV. 796 (1983) (Providing a comprehensive account of the development of products liability law); Hildy Bowbeer, Wendy F. Lumish & Jeffrey A. Cohen, *Warning! Failure to Read This Article May be Hazardous to Your Failure to Warn Defense*, 27 WM. MITCHELL L. REV. 439, 439 (2000) (Outlining failure-to-warn claims, which are 'among the most common allegations in products liability litigation'). Cf. Wexler, *supra* note 1, at 676 (Noting that the tDCS device 'market [for general consumers] may take care of itself. That is, absent a material price difference, consumers will opt for the safest and most effective product').

²¹ Indeed, this area of law serves the same function with regard to medical devices. Eg Efthimios Parasidis, *Patients Over Politics: Addressing Legislative Failure in the Regulation of Medical Products*, 2011 WISC. L. REV. 929, 933 (2011) ('Given the limitations of FDA review, tort law has traditionally served as a complementary means of regulating medical products and an additional layer of consumer protection').

²² 15 U.S.C. ch. 25, 26, 29, 33 (repealed), 35 (repealed), 36, and 86 (Instituting special regulations for the manufacture and sale of flammable fabrics, household refrigerators, switchblade knives, brake fluid (repealed), seat belts (repealed), cigarettes, and children's bicycle helmets).

²³ The FTC can monitor product effectiveness through its mandate to prevent unfair or deceptive commercial acts or practices, but it is hard to argue that this makes the focus on effectiveness under general consumer products regulation commensurate to that on safety.

device—which determines the degree of government oversight applied to it—is largely a function of risk, '[a]pproval [for use] requires a finding that the device is safe and effective—or, more accurately, provides benefits that outweigh its risks'.²⁴ And regulators determine the requisite benefit needed to offset any risk, not patients. This differs greatly from general product settings, where regulations and incentives push for risk disclosure and mitigation, but benefit assessment is largely left to consumers. Such a dichotomy is due to the comparably vulnerable position of patients, as noted above,²⁵ which supports the clinical finding of benefit and a government risk-benefit analysis prior to a device being approved for medical use.²⁶

We do, however, wish to briefly note an important concern. If devices marketed to general consumers are regulated such that safety is accounted for but effectiveness is left to user discretion, this potentially allows for the creation and mass consumption of devices that, while not harmful, have no actual effect. Such a situation could do significant damage to the field of tDCS research—eg diminish funding—if the technology gains an undeserved reputation for being a pseudoscience, or even worse, a scam.²⁷ But despite this worry, it is not the responsibility of the government to protect the scientific reputation of a technology, only the safety and freedom of its citizens.

With the proof of effectiveness facet of medical device regulation in mind, calls for the blanket application of this legal framework to all tDCS devices are presently unsubstantiated. The mere existence of risk, let alone its absence and simply an apprehension of risk, is a tenuous reason to label something a medical device and demand stringent showings of effectiveness. General products regulations take safety into account, and ordinary consumers, as opposed to patients, are capable of deciding whether a given device works for them. For these reasons, compelling tDCS devices marketed to the general public for cognitive enhancement to meet the same premarket approval requirements as medical devices would place an undue burden on producers. The differential regulation of the same product depending on the market for which it is intended is therefore not intrinsically inappropriate in this instance.²⁸

THE 'GAPS' IN FEDERAL tDCS DEVICE REGULATION

In her article, Wexler admirably demonstrates that there exists no general regulatory gap when it comes to tDCS devices. That is, even if a given device is not categorized as a medical device, an extensive regulatory framework still applies to it. But there has blossomed a body of scholarship contending that, rather than there existing a general

²⁴ Richard Merrill, *FDA Regulatory Requirements as Tort Standards*, 12 J. L. & POL'Y 549, 555 (2004) (emphasis added).

²⁵ *Supra* note 16.

²⁶ The FDA's 'paternalistic' place in this process has, however, been consistently debated, with many supporting the Administration's current role and others advocating for more patient involvement. Eg Lewis A. Grossman, *FDA and the Rise of the Empowered Patient*, in *FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES* 59–75 (Holly Fernandez Lynch & I. Glenn Cohen eds. 2015) (Presenting a general outline of this debate).

²⁷ Cf. Katherine Bourzac, *Bright Sparks*, 531 NATURE S6, S8 (2016) (Indicating that the widespread public availability of tDCS devices makes the technology appear to be 'snake oil' rather than a legitimate scientific apparatus).

²⁸ Cf. Wexler, *supra* note 1, at 684 ('[T]here are many 'dual use' products that are identical in technology but regulated differently based on intended use.').

regulatory gap with regard to tDCS devices, such gaps are present within the medical device and general products regulatory frameworks specifically.²⁹ We disagree.

Every argument for the amending of medical device rules to cover all tDCS devices explicitly or implicitly asserts that complementary gaps exist within both medical device and general products regulations.³⁰ The alleged gap in general products law is that this framework does not necessitate the proper level of inquiry into the safety and effectiveness of tDCS devices. But, as presented in the previous section, these regulations, though not as stringent as those for medical devices, address user safety fairly robustly, particularly given the overall lack of proven risk attendant with the use of tDCS devices. Moreover, intensive inquiries into device effectiveness are not inherently necessary when the product in question is not marketed to patients. As such, any gap in the coverage of tDCS devices under general products regulations has thus far failed to be convincingly presented. For these same reasons, coinciding contentions that medical device regulations contain a gap because they do not apply to all tDCS devices are also unpersuasive.

But, in addition, the language of federal medical device regulations does not necessarily exclude tDCS devices marketed to general consumers. As noted above, a device is legally a medical device if one of two conditions apply: (1) it is intended for therapeutic diagnosis or treatment; or (2) affects the structure or function of the body.³¹ These requirements are broad, and courts have given the FDA a great deal of deference in applying them.³²

It is the FDA that determines the intended use of a device, not the producer, although these determinations can be disputed in court.³³ Generally, the Administration looks to producer representations of the device to the public—ie labeling and advertising language.³⁴ But it can also consider a much wider array of factors: the circumstances surrounding product distribution, statements by manufacturers, instruction booklets, financial arrangements, shareholder reports, employee and third-party statements, and actual consumer use.³⁵ While these sources give producers the opportunity to influence the legal categorization of their products—and therefore the level of government scrutiny and regulatory burdens they are subjected to—the FDA ultimately has a broad space in which to look for qualifying representations and significant authority to construe language as it deems appropriate.³⁶ Moreover, the FDA's interpretations of intent

²⁹ *Supra* note 9.

³⁰ *Id.*

³¹ 21 U.S.C. § 321(h).

³² Andrew E. Costa, *Negligence Per Se Theories in Pharmaceutical & Medical Device Litigation*, 57 ME. L. REV. 51, 81 (2005) ('The broad grant of authority to the FDA, in conjunction with its scientific expertise, has earned the FDA a substantial degree of deference from the courts.').

³³ Deborah E. Tolomeo & Laurie A. Clarke, *Medical Devices: The Obvious, the Readily-Accepted, and the Surprising*, 1 J. HEALTH & LIFE SCI. L. 117, 136 (2008) ('Ultimately, FDA, rather than the manufacturer, determines whether a claim is for a health benefit.').

³⁴ Wexler, *supra* note 1, at 683–84; Tolomeo & Clarke, *supra* note 33, at 123 ('FDA generally infers the manufacturer's intended use of a product based on the manufacturer's claims about the product').

³⁵ Wexler, *supra* note 1, at 683–86; Tolomeo & Clarke, *supra* note 33, at 123–27.

³⁶ See Tolomeo & Clarke *supra* note 33, at 136. But see Wexler, *supra* note 1, at 679 ('[T]o a large extent, manufacturers can maintain control over how their products are regulated.').

are almost always accepted by courts when legally challenged.³⁷ Thus, if the FDA can essentially look wherever it wants to find a device's intended use for a medical purpose and is given substantial deference in these determinations, it is probable that it could legitimately envelope tDCS devices marketed to the general public for cognitive enhancement in its statutory authority.³⁸ And such action would likely withstand judicial scrutiny.

Yet even if the first relevant, and highly deferential, condition for being legally categorized as a medical device fails, the second arguably provides the FDA with an even broader mandate to apply its oversight. Certainly, if construed overly literally, the requirement that a device affect the structure or function of the body could theoretically encompass almost every product on the market.³⁹ The FDA and courts have therefore been fairly judicious in administering this condition, usually using it in conjunction with the medical purpose condition.⁴⁰ Nevertheless, devices' effects on the structure and function of the body have, at times, been liberally employed to capture them within the FDA's medical device regulatory authority, seemingly on their own.⁴¹ Given that tDCS devices explicitly introduce electricity into the brain to modulate the organ's operation,⁴² they clearly affect the body's structure or function. If the FDA chose to categorize tDCS devices targeting the general market under this condition, it is unlikely that courts would overturn such action.

For all of the aforementioned reasons, there does not presently exist a federal regulatory gap when it comes tDCS devices in either general products or medical device law. Instead, the current extents of coverage and levels of oversight of these frameworks are appropriate given current understandings of these instruments. Furthermore, any lack of application of medical device rules to tDCS devices marketed to general consumers for cognitive enhancement are most likely a function of FDA enforcement rather than limitations in regulatory language.

³⁷ *Supra* note 35. But see Wexler, *supra* note 1, at 685 (Noting a situation in which a court ruled against the FDA's extension of its authority over a product).

³⁸ See Tolomeo & Clarke, *supra* note 33, at 136 (Providing examples of products regulated as medical devices for simply 'conceivably hav[ing] a health-related purpose'). See also Fregni et al., *supra* note 7, at 23 ('Based on the FDA definition of a medical device, and recognizing the spectrum of devices regulated, it is thus logical to include tDCS devices—whether indicated for medical treatments, diagnostic purposes, wellness aids, entertainment devices, or for any other purpose—as a Medical Device according to the FDA.'). Cf. Maslen et al., *supra* note 8, at 79 (Presenting the argument that cognitive enhancement can be interpreted to be a medical purpose).

³⁹ See Wexler, *supra* note 1, at 681 ('[A] large number of products—from high-heeled shoes to chairs to treadmills—can be said to be intended to affect the body's structure or function.'). Action on Smoking and Health v. Harris, 655 F.2d 236, 240 (D.C. Cir. 1980) ('Anything which stimulates any of the senses may be said, in some perhaps insignificant degree, to affect the functions of the body of man . . . Surely, the legislators did not mean to be as all-inclusive as a literal interpretation of this clause would compel us to be.') (internal citations and quotation marks omitted).

⁴⁰ Eg Wexler, *supra* note 1, at 681 (Describing the restraint employed by the FDA and courts in applying the 'affects the structure or function of the body' condition).

⁴¹ This condition has extended the ambit of FDA medical device regulatory authority to several devices with a questionable medical purpose or ostensibly lacking one: alarms that sound when an elderly individual needs assistance, dental braces, and tanning beds. Tolomeo & Clarke, *supra* note 33, at 133–36.

⁴² Parazzini et al., *supra* note 2, at 1.

CONCLUSION

Legal frameworks should always remain attentive to technological progress, but such progress does not always militate toward substantial change. Accordingly, our work builds on that of Wexler to demonstrate that existing federal regulations applicable to tDCS devices are currently adequate for their responsible marketing to both patients and general consumers.