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Abstract

Several recent articles have called for the regulation of consumer transcranial direct current stimulation (tDCS) devices, which provide low levels of electrical current to the brain. However, most of the discussion to-date has focused on ethical or normative considerations; there has been a notable absence of scholarship regarding the actual legal framework in the United States. This article aims to fill that gap by providing a pragmatic analysis of the consumer tDCS market and relevant laws and regulations. In the five main sections of this manuscript, I take into account (a) the history of the do-it-yourself tDCS movement and the subsequent emergence of direct-to-consumer devices; (b) the statutory language of the Federal Food, Drug and Cosmetic Act and how the definition of a medical device—which focuses on the *intended use* of the device rather than its mechanism of action—is of paramount importance for discussions of consumer tDCS device regulation; (c) how both the Food and Drug Administration (FDA) and courts have understood the FDA's jurisdiction over medical devices in cases where the meaning of 'intended use' has been challenged; (d) an analysis of consumer tDCS regulatory enforcement action to-date; and (e) the multiple US authorities, other than the FDA, that can regulate consumer brain stimulation devices. Taken together, this paper demonstrates that rather than a 'regulatory gap,' there are multiple, distinct pathways by which consumer tDCS can be regulated in the United States.

Keywords

food and drug law, human enhancement, medical devices, neuroscience, regulation, transcranial direct current stimulation (tDCS)

Disciplines

Bioethics and Medical Ethics | Neuroscience and Neurobiology | Neurosciences



A pragmatic analysis of the regulation of consumer transcranial direct current stimulation (TDCS) devices in the United States

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ABSTRACT

Several recent articles have called for the regulation of consumer transcranial direct current stimulation (tDCS) devices, which provide low levels of electrical current to the brain. However, most of the discussion to-date has focused on ethical or normative considerations; there has been a notable absence of scholarship regarding the actual legal framework in the United States. This article aims to fill that gap by providing a pragmatic analysis of the consumer tDCS market and relevant laws and regulations. In the five main sections of this manuscript, I take into account (a) the history of the do-it-yourself tDCS movement and the subsequent emergence of direct-to-consumer devices; (b) the statutory language of the Federal Food, Drug and Cosmetic Act and how the definition of a medical device—which focuses on the *intended use* of the device rather than its mechanism of action—is of paramount importance for discussions of consumer tDCS device regulation; (c) how both the Food and Drug Administration (FDA) and courts have understood the FDA’s jurisdiction over medical devices in cases where the meaning of ‘intended use’ has been challenged; (d) an analysis of consumer tDCS regulatory enforcement action to-date; and (e) the multiple US authorities, other than the FDA, that can regulate consumer brain

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INTRODUCTION

Transcranial direct current stimulation (tDCS) is a non-invasive form of brain stimulation that is thought to provide a constant low level of electrical current to the brain. Approximately 1000 scientific studies have been published in peer-reviewed journals in the last decade,¹ many of which suggest the beneficial effects of tDCS in both clinical populations, for treating a variety of conditions and psychiatric disorders, and in healthy individuals, for enhancing everything from creative problem solving to the acquisition of motor skills.² Because a tDCS device is relatively easy to make (and cheap to acquire), there has arisen a movement wherein individuals stimulate their own brains with tDCS outside of research or medical settings for self-improvement purposes. The movement has been colloquially referred to as do-it-yourself (DIY) tDCS as it began with individuals constructing tDCS devices themselves. Since today many individuals who identify with the DIY tDCS movement purchase ready-made, direct-to-consumer (DTC) devices,³ the border between DIY and DTC has become muddled. In this paper, I refer to those who use tDCS devices outside of professional research and medical settings as ‘home users’. Thus, there currently exists two groups—researchers and home users—who utilize a single technology (sometimes even the exact same device) in very different ways. Whereas researchers apply tDCS to subjects within the controlled realm of the laboratory, home users apply tDCS on themselves, mostly in private settings, for cognitive enhancement or self-treatment.

Unsurprisingly, the use of tDCS outside of research settings has not been well received by scientists, many of whom believe that home users may ‘ruin it’ for the entire

¹ Pubmed title search for ‘transcranial direct current stimulation’ or ‘tDCS’, [http://www.ncbi.nlm.nih.gov/pubmed/?term=\(%22transcranial+direct+current+stimulation%22%5BTtitle%5D\)+OR+tdcs%5BTtitle%5D](http://www.ncbi.nlm.nih.gov/pubmed/?term=(%22transcranial+direct+current+stimulation%22%5BTtitle%5D)+OR+tdcs%5BTtitle%5D)

² For a review of clinical tDCS studies, see Min-Fang Kuo, Walter Paulus & Michael A. Nitsche, *Therapeutic Effects of Non-Invasive Brain Stimulation with Direct Currents (tDCS) in Neuropsychiatric Diseases*, 85 *NEUROIMAGE* 948 (2014); for tDCS in healthy populations, see Brian A. Coffman, Vincent P. Clark & Raja Parasuraman, *Battery Powered Thought: Enhancement of Attention, Learning, and Memory in Healthy Adults Using Transcranial Direct Current Stimulation*, 85 *NEUROIMAGE* 895 (2014). Note, however, that a few recent studies have questioned whether tDCS has any effect in healthy subjects, see eg Jared Cooney Horvath, Jason D. Forte & Olivia Carter, *Evidence That Transcranial Direct Current Stimulation (tDCS) Generates Little-to-No Reliable Neurophysiologic Effect Beyond MEP Amplitude Modulation in Healthy Human Subjects: A Systematic Review*, 66 *NEUROPSYCHOLOGIA* 213 (2015).

³ Anita Jwa, *Early Adopters of the Magical Thinking Cap: A Study On Do-It-Yourself (DIY) Transcranial Direct Current Stimulation (tDCS) User Community*, 2 *J. L. BIOSCI.*, 292, 307 (2015).

academic field.⁴ Researchers have publicly voiced their concerns: a 2013 *Nature* editorial stated that ‘to try to boost cognitive performance in this way might be a very bad idea indeed’.⁵ One tDCS researcher published a letter in *Nature* titled ‘Transcranial devices are not playthings’ writing: ‘Unorthodox technologies and applications must not be allowed to distort the long-term validation of tDCS’.⁶ In addition, scientists have urged caution regarding the uncontrolled use of tDCS: although no serious adverse events have been reported among the 10,000 subjects studied to date,⁷ at least one study has found that tDCS can impair cognitive function in some individuals.⁸

Currently, tDCS is not approved in the United States by the Food and Drug Administration (FDA) as a medical treatment for any indication. Researchers (but not the general public) may obtain tDCS devices for investigational use from either Soterix or Neuroconn, the two US companies whose devices have an ‘investigational device exemption’ from the FDA.⁹ However, as the Soterix and Neuroconn models cost thousands of dollars, some researchers have opted to repurpose cheaper iontophoresis devices (current-providing machines used to treat various conditions, such as excessive sweating) for tDCS use. By contrast, consumer tDCS devices—which are not regulated as medical or investigational devices—are available to the public; there are currently at least a half dozen devices on the market ranging in price from \$49 to \$299.

Several scientists and neuroethicists have argued that there is a need for additional regulation to cover consumer tDCS devices.¹⁰ One paper proposed extending medical device regulation in Europe to include not just tDCS devices but also consumer electroencephalography (EEG) devices, which passively record electrical brainwaves and display them to users.¹¹ (I focus here only on non-invasive electrical brain stimulation devices, because as has been previously pointed out, EEG devices in themselves are measuring tools, akin to heart-rate monitors.)¹² Some scholars have written extensively about the moral and ethical considerations related to non-invasive brain

⁴ According to the results of a questionnaire distributed at the 2015 New York City Neuromodulation Conference, researchers believe that one of the main issues facing the field over the next 15 years is the ‘DIY community ruining it for the rest of us’. Conference Questionnaire Results, Presented on Jan. 11, 2015 at the New York City Neuromodulation Conference, New York, Jan. 9–11, 2015; <http://neuromodec.com/events/nyc-neuromodulation-conference-2015/> (accessed Aug. 25, 2015).

⁵ Editorial, *Brain Blast*, 498 NATURE 271, 272 (2013).

⁶ Marom Bikson, Sven Bestmann & Dylan Edwards, *Neuroscience: Transcranial Devices Are Not Playthings*, 501 NATURE 167 (2013).

⁷ Felipe 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. REGUL. AFF., 22, published online first Dec. 2 2014.

⁸ Amar Sarkar, Ann Dowker & Roi Cohen Kadosh, *Cognitive Enhancement or Cognitive Cost: Trait-Specific Outcomes of Brain Stimulation in the Case of Mathematics Anxiety*, 34 J. NEUROSCI. 16605 (2014).

⁹ Fregni et al., *supra* note 7 at 10. See also Soterix Medical, <http://soterixmedical.com/tdcs> and Jali Medical (US distributor for Neuroconn) http://www.jalimedical.com/neuroconn_dc_stimulator_mc.html (accessed Sep. 22, 2015).

¹⁰ See eg Veljko Dubljevic, *Neurostimulation Devices for Cognitive Enhancement: Toward a Comprehensive Regulatory Framework*, 8 NEUROETHICS 115 (2015); Hannah Maslen et al., *Do-it-Yourself Brain Stimulation: A Regulatory Model*, 41 J. MED. ETHICS 413 (2015).

¹¹ Hannah Maslen et al., *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, 1 J. L. BIOSCI. 68 (2014).

¹² Andreas Kuersten & Roy H. Hamilton, *The Brain, Cognitive Enhancement Devices, and European Regulation*, 1 J. L. BIOSCI. 340 (2014).

stimulation.¹³ Others have argued that there is a need for greater engagement with the DIY brain stimulation community.¹⁴ Collectively, existing scholarship has contributed important normative and ethical perspectives on the regulation of such devices.

Missing from this literature, however, are accounts that consider the practicalities of the law and how it applies to existing and foreseeable consumer brain stimulation devices. For example, as I will show in Part I below, an examination of the current tDCS consumer device market reveals that the recommended extension of medical device regulation in Europe would apply to only a small sliver of devices, rendering it largely ineffective.¹⁵ Furthermore, many proposals neglect to consider the practical differences between regulation and regulatory enforcement. Though an ideal model of the law envisions all regulations as being consistently and equally enforced, a more realistic view takes into account the resource-constrained nature of government bodies, who must formally, and sometimes informally, prioritize regulatory enforcement and often do so in unclear or unsystematic ways. Thus, before calling for additional regulation or concluding that there is a ‘regulatory gap’,¹⁶ it must first be determined that the problem is the lack of regulation, not the lack of enforcement.

It is also crucial to consider the precise statutory language of existing regulation. For example, in the United States, the FDA makes its determination of whether a product is a medical device based on the *intended use* of the device as stated by the manufacturer—not based on the mechanism of action of the device itself. One recent paper co-authored by tDCS experts failed to take into account the intricacies of the statute, stating that it would be ‘logical to include tDCS devices’ as medical devices according to the FDA, regardless of ‘whether indicated for medical treatments, diagnostic purposes, wellness aids, entertainment devices, or any other purpose...’¹⁷ However, legal authority carves up jurisdiction much more finely than this logic suggests. Within current statutory definitions, products marketed for entertainment or wellness purposes would *not* fall under the scope of the FDA (as long as they make no medical-related claims about modifying the structure or function of the body, as will be discussed in Part II below), whereas a device intended for medical treatment or diagnosis would indeed be regulated as a medical device.

This paper contributes to the literature on the regulation of consumer brain stimulation devices in the USA by providing a fact-based analysis of the consumer tDCS market and relevant laws and regulations. In the first section, I present a short history of the DIY tDCS movement and the subsequent emergence of DTC devices. In the second and third sections, I outline the basics of FDA medical device regulation and discuss how the definition of a medical device—which focuses on the *intended use* of the device rather than its mechanism of action—is of paramount importance for

¹³ See eg Roy Hamilton, Samuel Messing & Anjan Chatterjee, *Rethinking the Thinking Cap: Ethics of Neural Enhancement Using Noninvasive Brain Stimulation*, 76 NEUROLOGY 187 (2011); Roi Cohen Kadosh et al., *The Neuroethics of Non-Invasive Brain Stimulation*, 22 CURR. BIOL. R108 (2012).

¹⁴ Nicholas S. Fitz & Peter B. Reiner, *The Challenge of Crafting Policy for Do-It-Yourself Brain Stimulation*, 41 J. MED. ETHICS 410 (2015).

¹⁵ Anna Wexler, *The Practices of the Do-It-Yourself Brain Stimulation Community: Implications for Regulatory Proposals and Ethical Discussions*, J. MED. ETHICS, DOI:10.1136/medethics-2015-102704.

¹⁶ Veljko Dubljevic, Victoria Saigle & Eric Racine, *The Rising Tide of tDCS in the Media and Academic Literature*, 82 NEURON 731, 736 (2014).

¹⁷ Fregni et al., *supra* note 7 at 2.

discussions of consumer tDCS device regulation. I then discuss how both the FDA and the courts have understood the FDA's jurisdiction over medical devices in cases where the meaning of 'intended use' has been challenged. In the fourth section, I analyse the only instance of tDCS regulatory action to date, in which the California Department of Public Health (CDPH) forced a firm to recall several hundred consumer tDCS devices. Although there exists a common perception that the FDA has not been involved with the regulation of consumer tDCS devices, the California case demonstrates that the CDPH's actions were instigated by an FDA engineer. Finally, I discuss the multiple US authorities, other than the FDA, that can regulate consumer brain stimulation devices.

In sum, this paper dispels the notion of a 'regulatory gap' with regard to consumer non-invasive brain stimulation (in the United States). Several papers—mostly those focusing on the appropriate 'level' of regulation—seem to have assumed that additional regulation is the de facto appropriate response to the existence of consumer tDCS devices. I argue, however, that there already exists a comprehensive regulatory framework for both consumer and medical tDCS devices in the United States. Thus, rather than calling for additional regulation, I suggest the need for a practical approach to consumer brain stimulation devices, one that outlines relevant issues of concern and considers multiple ways of addressing them.

I. From DIY to DTC—a short history of the consumer tDCS device market

The earliest mentions of DIY brain stimulation date back to 2007, in an online forum posting on Longecity.org¹⁸ and in an article *The Phoenix*, which described how one individual tried to treat his depression using a tDCS device he constructed by modifying a Radio Shack Electronics Learning Lab.¹⁹ Home use of tDCS seems to have remained isolated until mid-2011, when a Yahoo group²⁰ and a Reddit forum (called a 'subreddit') dedicated to DIY tDCS were formed.²¹ By early 2012, there were a number of blogs and sites dedicated exclusively to the topic, indicating that individuals were utilizing tDCS for both self-treatment and cognitive enhancement purposes.

What factors contributed to the rise of DIY tDCS? The appearance of the movement corresponds to the increase in popularity of tDCS in scientific journals: in 2011, there were over 130 peer-reviewed articles about tDCS, more than double that of the previous year.²² The following year, 2012, saw the greatest quantitative increase in mentions of tDCS in the popular press.²³ In addition, DIY tDCS shares characteristics with related movements that were well established by 2010, such as DIY biology and

¹⁸ *Attaching a battery to your head*, LONGECITY, 2007, <http://www.longecity.org/forum/topic/19346-attaching-a-battery-to-your-head/> (accessed Sep. 22, 2015).

¹⁹ Pagan Kennedy, *Brain-O-Matic*, BOSTON PHOENIX, Feb. 7, 2007, <http://thephoenix.com/boston/life/33313-brain-o-matic/> (accessed Sep. 22, 2015).

²⁰ Yahoo Transcranial Direct Current Stimulation group, <https://groups.yahoo.com/neo/groups/tDCStim/info> (accessed Sep. 22, 2015).

²¹ Reddit /r/tDCS (<http://www.reddit.com/r/tDCS/>) began in April 2011. E-mail from moderator of r/tDCS to Anna Wexler (Feb. 17, 2015), on file with author.

²² *Supra* note 1.

²³ According to one study, there were roughly three-dozen print media articles about tDCS in 2011, and nearly 70 in 2012. See Dujbjevic et al., *supra* note 16, at 732.

quantified self.²⁴ Finally, and perhaps most importantly, although there are other methods of stimulating the brain with electricity or magnetism, tDCS is unique in that the stimulation device is both non-invasive (ie no surgical implantation is required) and relatively inexpensive to acquire or create.²⁵

During the early days of the DIY tDCS, most individuals built their devices from scratch, with the help of diagrams posted online and electronics assistance from other DIYers. At its core, a tDCS device contains a current-providing component (such as a 9 V battery), wires that plug into the current source, and electrodes that interface between the wire and the skin. When both electrodes are connected to the scalp, the electrical circuit closes, and current is thought to flow through the brain.²⁶ This simple construction—battery, wires, and electrodes—forms the essence of a tDCS device. Compared to other techniques that stimulate the brain with electricity, such as electroconvulsive therapy (ECT), the level of current used in tDCS is relatively low: most tDCS studies use 0.5–2 mA, whereas ECT utilizes 500–900 mA.²⁷

The notion of a ready-to-wear consumer tDCS headset first hit the media in the spring of 2012, when two undergraduates from the University of Michigan, Matt Sornson and Nick Woodhams, built a prototype of a tDCS device called the GoFlow (‘the world’s first tDCS kit’) and promised to sell it for \$99.²⁸ Various press outlets picked up on the story, enthusiastically describing the initiative with headlines such as ‘Buy a DIY Brain Supercharger for \$100’ and ‘Transcranial direct current stimulation works, and you can try it at home’.²⁹ Two months later, in May 2012, the company announced that they were being delayed due to FDA concerns,³⁰ and in early 2013 the co-founders made the decision to abandon plans for the headset.³¹ Rumors swirled online that the GoFlow team ‘ran into some problems’ with the FDA.³² But Sornson had not been

²⁴ Both DIY Biology and DIY tDCS embody what has become known as the maker culture, which places a high value on tinkering, engineering, and creating things from scratch. For DIY Biology, see eg <http://diybio.org/> and ALESSANDRO DELFANTI, *BIOHACKERS: THE POLITICS OF OPEN SCIENCE* (2013). Both DIY tDCS and the quantified self-movement share the same underlying goal of self-improvement and self-optimization; see eg Melanie Swan, *The Quantified Self: Fundamental Disruption in Big Data Science and Biological Discovery* 1 *BIG DATA* 85, 87 (2013).

²⁵ By comparison, deep brain stimulation, a treatment for Parkinson’s disease that provides electrical stimulation to the brain, requires neurosurgery. Transcranial magnetic stimulation, an FDA-approved treatment for depression, is non-invasive, but the stimulation device is not easy to replicate.

²⁶ For a view that current is not entering the cortex and only affecting cranial nerves, see William J. Tyler et al., *Suppression of Human Psychophysiological and Biochemical Stress Responses Using High-Frequency Pulse-Modulated Transdermal Electrical Neurosignaling*, *BIOXRIV* preprint, first published online Feb. 8, 2015, doi.org/10.1101/015032

²⁷ American Psychiatric Association, *The Practice of Electroconvulsive Therapy: Recommendations for Treatment, Training and Privileging*, 147 (2d ed. 2000).

²⁸ *GoFlow*, <http://www.flowstateengaged.com> (accessed Mar. 2012). <http://web.archive.org/web/20120314201106/http://flowstateengaged.com/>

²⁹ Ashlee Vance, *Buy a DIY Brain Supercharger for \$100*, *BLOOMBERG BUSINESSWEEK*, Mar. 21, 2012, <http://www.businessweek.com/articles/2012-03-21/buy-a-diy-brain-super-charger-for-100> (accessed Sep. 22, 2015); Christopher Mims, *DIY Kit Overclocks Your Brain With Direct Current*, *MIT TECHNOLOGY REVIEW*, Mar. 8, 2012, <http://www.technologyreview.com/view/427177/diy-kit-overclocks-your-brain-with-direct-current/> (accessed Sep. 22, 2015).

³⁰ *Go Flow Kickstarter Campaign Denied*, *DIYTDCS*, <http://www.diytdcs.com/2012/05/goflow-kickstarter-campaign-denied/> (accessed Dec. 14, 2013).

³¹ Interview with Matt Sornson, co-developer of GoFlow, Feb. 14, 2014.

³² Longcity Forum, <http://www.longcity.org/forum/topic/57869-increased-cognition-with-9v-battery/>

contacted by the FDA; rather, he and Woodhams abandoned the GoFlow for personal reasons, though potential future complications with the FDA were also a factor in their decision.³³ The company quietly sold their mailing list and domain name to a firm building a consumer tDCS device called the Foc.us,³⁴ and in June 2013 announced that they would not be moving forward with the project.³⁵

In the year between Sornson's and Woodham's start up and shut-down announcements, a number of other consumer tDCS devices appeared on the market: Hong Kong-based Trans Cranial Technologies³⁶ began selling a \$379 device, and at least three other websites offered more affordable tDCS device 'kits'.³⁷ The kits varied in both price and level of sophistication, but usually consisted of a 9 V battery enclosure (or a snap connector that the battery attached to), wires, electrodes, and a headband to facilitate electrode placement. They were seemingly geared to those who had knowledge of tDCS but lacked the necessary soldering skills to build their own device from scratch. Some home users, like scientists, began purchasing and repurposing iontophoresis devices, which legally require a prescription but in practice are widely available online.³⁸

The Foc.us device, which was released in the summer of 2013, was arguably the first true DTC tDCS device.³⁹ With its sleek, ready-to-wear headset design, it looked more like Google Glass than a cobbled-together DIY device. The company's website, advertising campaign (featuring photos of an attractive woman wearing the device), and promised smartphone integration made it clear that the product was a step up from the kits sold by small-scale vendors. Though the Foc.us device was ostensibly marketed to gamers, its release thrust the DIY tDCS movement into the spotlight and brought the debate over the regulation of cognitive enhancement devices to public attention.⁴⁰

Since 2013, thousands of Foc.us devices have been sold⁴¹ and the company has released a second generation of products; it currently has a headset specially designed for exercise.⁴² New consumer tDCS devices are constantly appearing on the market,

³³ E-mail from Matt Sornson, co-developer of GoFlow, to Anna Wexler (Dec. 15, 2013), on file with author.

³⁴ *Supra* note 31.

³⁵ *Id.* and *News from GoFlow! Good and Bad*, DIYTDCS, <http://www.diytdcs.com/2013/06/news-from-goflow-good-and-bad/> (accessed Dec. 14, 2013).

³⁶ Trans Cranial Technologies, <http://www.trans-cranial.com/> (accessed July 1, 2014); note that the company is currently conducting business as TCT Research Limited.

³⁷ See www.biocurrentkit.com, www.tdcs-kit.com, and www.tdcsdevicekit.com, accessed between Dec. 2012 and Apr. 2013, archived versions at <http://web.archive.org>

³⁸ See eg <http://www.amazon.com/DSS-Chattanooga-Ionto/dp/B00FC2SRMY> and <http://www.isokineticsinc.com> (accessed Sep. 22, 2015).

³⁹ FOC.US, *Transcranial Direct Current Stimulation for Gamers*, <http://www.foc.us/> (accessed July 8, 2013), <http://web.archive.org/web/20130708144009/http://www.foc.us/>

⁴⁰ See eg Kate Murphy, *Jump-Starter Kits for the Mind*, THE NEW YORK TIMES, Oct. 28, 2013, <http://www.nytimes.com/2013/10/29/science/jump-starter-kits-for-the-mind.html> (accessed Sep. 22, 2015); Nick Statt, *When Wearable Tech Makes You Smarter—by Zapping Your Brain*, CNET, Aug. 9, 2013, <http://news.cnet.com/8301-11386-3-57597116-76/when-wearable-tech-makes-you-smarter-by-zapping-your-brain/> (accessed Sep. 22, 2015).

⁴¹ Although sales data for the Foc.us device are not public, the company sold out its first production run of 3000 within a month (Murphy *supra* note 40) and has since had several production runs.

⁴² *Foc.us edge tDCS headset*, <http://www.foc.us/edge-tdcs-headset> (accessed Jan. 25, 2015).

most often manufactured in small runs by individuals interested in, or involved with, the DIY tDCS movement. Though the prospect of regulation looms large for many of these manufacturers, the only legal action to date has come at a state level, from the CDPH, which effectively halted sales from tdcsdevicekit.com in May 2013 (the case is discussed in detail in Part IV below).

In 2014, two Silicon Valley start-ups announced that they were entering the consumer brain stimulation device market. One company, Halo Neuroscience, issued a press release in May 2014, noting that it had received \$1.5 million in venture capital funding and was developing ‘wearable technology that boosts brain function’.⁴³ The company’s board includes well-known names such as Reed Hundt, former chairman of the Federal Communications Commission (FCC).⁴⁴ In October 2014, a company named Thync announced that it had raised \$13 million in venture capital funding.⁴⁵ In June 2015, the company released its device (\$299), which is controlled via smartphone and provides a form of non-invasive brain stimulation for mood alteration purposes (either a ‘calm vibe’ or an ‘energy vibe’).⁴⁶ The company has reportedly tested thousands of subjects, both on its own and in collaboration with tDCS researchers, and has posted some of its results online.⁴⁷ Given that both Halo Neuroscience and Thync are well funded and highly connected, consumer non-invasive electrical brain stimulation is certain to hit the mainstream public in the near future. Thus, what began as DIY brain stimulation is likely to be superseded by—or at least dwarfed by—DTC brain stimulation.

At present, however, the border between DIY and DTC remains muddled. Qualitative research has shown that while some individuals from the DIY tDCS movement build their own devices, others acquire a wide range of devices, from device ‘kits’ (which require assembly) and iontophoresis devices (which require repurposing) to the Foc.us headset.⁴⁸ Given the variation in existing consumer tDCS devices, the consumer non-invasive brain stimulation market does not lend itself easily to regulation. Indeed, the proposed extension of medical device regulation in Europe would apply only to true DTC headsets; it would not encompass self-built devices and iontophoresis devices, and it is unclear whether it would cover ‘kits’.⁴⁹ Furthermore, if the devices from Thync and Halo Neuroscience are sold at competitive price points, it is possible that the market may take care of itself. That is, absent a material price difference, consumers will opt for the safest and most effective product. As companies such as Thync have already

⁴³ Halo Neuroscience—Press Release (May 28, 2014) <http://haloneuro.com/press/> (accessed Jan. 25, 2015).

⁴⁴ Halo Neuroscience, <http://haloneuro.com/> (accessed Jan. 25, 2015).

⁴⁵ Brad Stone, *Thync Lets You Give Your Mind a Jolt*, BLOOMBERG BUSINESS, Oct. 8, 2014, <http://www.bloomberg.com/bw/articles/2014-10-08/thync-raises-13-million-for-its-brain-stimulating-electrodes> (accessed Sep. 22, 2015).

⁴⁶ *Id.* and Thync.com (accessed Sep. 22, 2015).

⁴⁷ The safety section of Thync’s website states: ‘Thync Vibes were safely tested on several thousand individuals under a variety of conditions to optimize their performance and comfort.’ *Thync—Safety*, <http://www.thync.com/science-and-technology> (accessed June 25, 2015). See also Tyler et al., *supra* note 26.

⁴⁸ Jwa, *supra* note 3; Wexler, *supra* note 15.

⁴⁹ Wexler, *supra* note 15.

been in dialog with the FDA,⁵⁰ it is unclear how additional regulation—which could take years to implement—might fit into the overall picture.

II. The importance of ‘intended use’ for FDA medical device regulation

Prior to 1976, medical devices were not required to secure FDA approval before being marketed.⁵¹ But after a series of tragedies related to the implantation of pacemakers and intra-uterine devices,⁵² Congress passed the Medical Device Amendments in 1976,⁵³ which set up a new regulatory scheme for devices, classifying them based on risk level.⁵⁴ Class I devices are low-risk devices, such as band-aids and examination gloves, which are subject to ‘general controls’ (eg registration of facilities, device labeling, compliance with good manufacturing practices).⁵⁵ Class II devices are moderate risk devices, such as surgical drapes and breast pump kits, and are subject to additional ‘special controls’ that vary by product (eg performance standards, special labeling, and post-market surveillance).⁵⁶ To date, most devices that provide a low level of electrical stimulation to the body for medical purposes, such as transcutaneous electrical nerve stimulation (TENS) devices and powered muscle stimulation devices, are considered Class II devices.⁵⁷ Class III devices are those that pose a high risk of illness or injury.⁵⁸ The only Class III non-invasive electrical stimulation devices are cranial electrotherapy stimulation (CES) devices and some iontophoresis devices, though in 2014 the FDA indicated that it planned to recategorize both as Class II.⁵⁹ Prior to being marketed, a new class III device must submit a premarket application (PMA) demonstrating safety and efficacy for a specific indication.⁶⁰ The PMA process, which is similar to the new drug approval process, is often a multi-year, multi-million dollar endeavor. Thus, most medical device manufacturers take a faster and cheaper path to market, by filing a 510(k) application to demonstrate ‘substantial equivalence’ to a ‘predicate’ device.⁶¹ In 2011, nearly 99 per cent of new medical devices were cleared by the FDA through the 510(k)

⁵⁰ *Infra* notes 84 and 85.

⁵¹ PETER BARTON HUTT ET AL., FOOD AND DRUG LAW, 1201 (4d ed. 2014).

⁵² *Id.* at 1202, 1205.

⁵³ Medical Device Amendments of 1976, Pub.L. No. 94–295, 90 Stat. 539.

⁵⁴ 21 U.S.C. § 360c(a)(1) (2012).

⁵⁵ *Id.* and US Food and Drug Administration, *Regulatory Controls (Medical Devices)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm> (accessed Sep. 22, 2015).

⁵⁶ *Id.*

⁵⁷ See Fregni et al., *supra* note 7, at 2; and eg 21 C.F.R. §§882.5890, §§882.5891, and §§882.5810 (2015).

⁵⁸ 21 U.S.C. § 360c(a)(1) (2012).

⁵⁹ For CES devices, see Food and Drug Administration, 79 Fed. Reg. 33,712 (June 12, 2014) (codified at 21 C.F.R. 882), <https://www.federalregister.gov/articles/2014/06/12/2014-13756/neurological-devices-withdrawal-of-proposed-effective-date-of-requirement-for-premarket-approval-for> (accessed Sep. 22, 2015). See also *infra* notes 63 and 128. For iontophoresis devices, see Food and Drug Administration, 79 Fed. Reg. 56,532 (proposed Sept. 22, 2014) (to be codified at 21 C.F.R. pt. 890), <https://www.federalregister.gov/articles/2014/09/22/2014-22453/reclassification-of-iontophoresis-devices-intended-for-any-other-purposes>.

⁶⁰ 21 U.S.C. § 360c(a)(1) and US Food and Drug Administration, *Premarket Approval*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm2007514.htm> (accessed Jan. 25, 2015).

⁶¹ Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 360(k)) (2012) and 21 CFR § 807.92(a)(3) (2015).

process.⁶² Note, however, that most new Class III devices (which require PMAs) cannot be cleared via the 510(k) process.⁶³

While the level of risk determines the regulatory process for medical devices, a product must first meet the definition of a medical device to fall within the regulatory jurisdiction of the FDA. According to Section 201(h) of the Food, Drug & Cosmetic (FD&C) Act, a medical device is:

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - 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
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.⁶⁴

Importantly, the definition of a medical device is not based on the mechanism of action of the device, but rather on its intended use: a product is a medical device if it is *intended for use* in diagnosis or treatment, or *intended to affect* the structure or function of the body. Similar wording appears in the definition of a drug, and ‘intended use’ language dates all the way back to the Federal Food and Drugs Act of 1906.⁶⁵

How does the FDA establish intended use? According to the code of federal regulations Title 21, part 801, subpart A, Section 801.4 (‘meaning of intended uses’), it focuses on ‘the objective intent of the persons legally responsible for the labeling of

⁶² Hutt et al., *supra* note 51, at 1219 (‘In 2011, FDA cleared 3,072 premarket notifications while approving only 37 PMAs. In other words, approximately 98.8 percent of new devices cleared for marketing by FDA that year were cleared under section 510(k) rather than by PMA.’).

⁶³ The only case wherein new Class III devices can be cleared via the 510(k) process is if the devices are substantially equivalent to certain ‘preamendment’ (ie introduced to the market before May 28, 1976) Class III devices. When the new regulatory scheme for medical devices took effect in the late 1970s, the FDA temporarily classified over 100 devices as Class III devices. Such devices were never required to submit PMAs showing safety or efficacy. It has taken the FDA several decades to ‘reclassify’ these devices—either into Class I or Class II, or sustain the Class III classification but require a PMA—and currently there are less than 20 such devices awaiting FDA action. Thus, if a new (‘postamendment’) device can demonstrate substantial equivalence to one of the few devices that were temporarily classified as Class III devices and have yet to be reclassified, the device can be cleared via the 510(k) process. See *infra* note 128 and related text for the discussion of one example, a CES device. US Food And Drug Administration, *515 Program Initiative*, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm> (accessed Sep. 22, 2015).

⁶⁴ Section 201(h) of the FFDCA (21 U.S.C. § 321(h)) (2012); guidance to industry <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm> (accessed Sep. 22, 2015).

⁶⁵ Section 6, 34 Stat. 768, 769 (1906).

devices' as shown on both the product's labels and advertising.⁶⁶ That is, the product is classified according to the manufacturer's representation of it. Thus, to a large extent, manufacturers can maintain control over how their products are regulated. Indeed, this was the legislative intent: a 1935 Senate report noted that the 'manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing the article fairly and unequivocally as a drug product'.⁶⁷

A product's classification as a drug or device can have far-reaching consequences: as mentioned above, new drugs (and many new devices, if they cannot demonstrate substantial equivalence to a predicate device) must undergo costly clinical trials to demonstrate safety and efficacy, and it often takes several years to obtain FDA approval. In some industries, such as cosmetics, which have lenient regulatory requirements as compared to drugs, manufacturers take great pains to ensure that their advertising and product labels do not make disease or structure/function claims. It is no exaggeration to say that a manufacturer's fate may hinge on specific word choices. In the classic example, a cream that claims to 'reduce wrinkles' will be classified as a drug (and subject to stringent regulatory requirements) because the wording makes a specific structure/function claim, but a cream that claims to 'reduce the appearance of wrinkles' will be classified as a cosmetic because the language makes a beautification claim, not a structure/function one.⁶⁸

Given the importance of intended use claims for the classification of drugs and devices, it is worthwhile to examine how manufacturers of consumer tDCS devices have represented their products. As can be seen in Table 1, the overall intended use implied by most manufacturers (based on their websites) is related enhancement or optimization of brain function. Two manufacturers (TCT Research Limited⁶⁹ and PriorMind, both based in Hong Kong) make explicit disease claims about their products. Several other manufacturers mention, or link to, studies on the therapeutic use of tDCS, while others refrain from referring to any such research. One manufacturer, Super Specific Devices, makes no claims at all.

⁶⁶ The text of 21 C.F.R. § 801.4 reads as follows:

'The words intended uses... refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.'

⁶⁷ This Senate report accompanied one of precursor bills to the FD&C. S.Rep. No. 493, 73d Cong., 2d Sess. 2–3 (1934), reprinted in 2 *Legislative History*, 721, 722–23.

⁶⁸ For comprehensive discussion, see Peter Barton Hutt, *The Legal Distinction in the United States Between a Cosmetic and a Drug*, in *COSMECEUTICALS* 223, 240 (Peter Elsner & Howard I. Maibach eds., 2000).

⁶⁹ TCT Research Limited previously conducted business as TCT Technologies, see *supra* note 36, but its website (www.trans-cranial.com) remained the same.

Table 1. Marketing language from the websites of consumer tDCS devices available for purchase as of June 2015.

CONSUMER TDCS DEVICE	MARKETING LANGUAGE
Brain Stimulator* https://thebrainstimulator.net/what-is-tdcs/	'tDCS allows you to unlock your brain's true potential'
Cognitive Kit* http://www.cognitivekit.com/	'Charge your mind'
tdcs-kit http://www.tdcs-kit.com/	'Power your mind'
ApeX Type A* http://www.apexdevice.net/	'Be happier. Be focused. Be smarter'
Foc.us* http://www.foc.us/	'make your synapses fire faster', 'overclock your brain', 'take charge'
Thync* http://www.thync.com	'quiet your mind', 'boost your workout'
PriorMind http://www.priormind.com	'increase your attention span' 'tDCS has been widely used to treat depression...'
TCT* http://www.trans-cranial.com	'when only the best in tDCS therapy will do'
Super Specific Devices* http://www.superspecificdevices.com	'personal tDCS device'

*Website contains some form of a medical or health-related disclaimer.

Furthermore, it seems that at least some manufacturers have attempted to write around the provisions of the FDA. Seven of the nine manufacturers display some form of health or medical-related disclaimer on their websites, noting either that their product is not a medical device or that it is not intended to cure, treat, or diagnose diseases. To date, at least two manufacturers of tDCS devices have used the term 'kit' in hopes that it would put distance between their product and the FDA's definition of a medical device.⁷⁰

While products that make explicit or implied disease claims would be classified as medical devices, it is less clear whether those that mention, or link to, tDCS research could be considered medical devices. For example, while a link to a study describing the benefits of tDCS for depression may be considered an implied medical claim, noting that scientists are studying the use of tDCS for various indications may not be. Each manufacturer's claim and product would have to be reviewed in their own contexts.

⁷⁰ Richard O'Rourke of www.tDCSdevicekit.com (which does not appear in Table 1 because it shut down in 2013) stated this to a California Department of Health investigator, see Part IV and *Medical Device Investigative Report*, *infra* note 116. A manufacturer of one of the device kits in Table 1 stated: 'I came up with the idea of a kit, skirting the line a little bit... it's a kit... it's not a TDCS device'. Interview with manufacturer (Mar. 27, 2014).

Although such individual reviews are outside the scope of this paper, the issue of implied therapeutic claims is considered again in Part IV, in the discussion of the regulatory enforcement action taken by the CDPH against a small-scale consumer tDCS manufacturer.

The more complex question, however, is whether language such as ‘power your mind’ and ‘increase your attention span’ implies an intended structure/function claim. The FDA and courts have struggled to interpret the meaning of ‘intended to affect the structure or any function of the body...’ as 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. In general, both the FDA and courts have recognized that interpreting the statute literally would lead to a large number of consumer products coming under FDA regulation. For example, in one case, the D.C. Circuit court noted that Congress surely did not mean for there to be a broad reading of ‘intended to affect the structure or function...’ because otherwise a multitude of products—anything that ‘stimulates the senses’—could be considered a medical device or drug.⁷¹

Instead, courts have leaned toward a narrow interpretation of the statute, in which a structure/function claim must have a medical or therapeutic connotation. Three cases in particular, related to seizures of wrinkle remover creams in the 1960s, have served to clarify this interpretation. In *United States v. An Article...Sudden Change*, an appeals court ruled that the question of whether a product is to ‘intended to affect the structure or function of the body’ hinged on whether the claim may be said ‘to constitute a representation that the product will affect the structure of the body in some medical or drug-type fashion’.⁷² In *United States v. An Article of Drug...Helene Curtis Magic Secret*, a district court also upheld that a ‘drug connotation’ was necessary for a claim to be considered a structure/function one.⁷³ In *United States v. An Article of Drug... Line Away*, an appeals court ruled that the Line Away product was a drug, because its structure/function claims had therapeutic implications.⁷⁴ Though the latter three cases relate to drugs, the ‘intended to affect...’ clause is identical for drugs and medical devices.

Indeed, in a 2002 letter, FDA Chief Counsel Daniel Troy stated that the Food, Drug, and Cosmetic Act regulates only those devices whose claims have medical or therapeutic connotations.⁷⁵ In the letter, which can be said to reflect the FDA’s most recent explication of its position on intended use and structure/function claims, the FDA determined that an implantable radio-frequency identification chip intended for health applications was considered a medical device, whereas the same chip intended for use only in security and personal identification applications was not. Thus, even an implantable device—one that clearly affects the structure or function of the body in some manner—was considered a medical device by the FDA only when its intended use was medically related.

With regard to consumer tDCS devices, would ‘brain optimization’ or ‘cognitive enhancement’ claims be considered to have medical or therapeutic connotations?

⁷¹ Action on Smoking and Health v. Harris, 655 F.2d 236, 240 (D.C. Circuit 1980).

⁷² United States v. An Article... Sudden Change, 409 F.2d 734 (2d Cir. 1969).

⁷³ United States v. An Article of Drug... Helene Curtis Magic Secret, 331 F. Supp. 912 (D. Md. 1971).

⁷⁴ United States v. An Article of Drug... Line Away, 415 F.2d 369 (3d Cir. 1969).

⁷⁵ Letter from FDA Chief Counsel Daniel E. Troy to Jeffrey N. Gibbs (Oct. 17, 2002).

Indeed, the issue of what sorts of ‘optimization’ claims are permissible for consumer devices has become a pressing one in recent years, due to the increase in wearable technology devices and smartphone-based health applications. In at least some industries, it is thought that ‘wellness’ claims (eg ‘supports sleep’) as opposed to therapeutic ones (eg ‘reduces insomnia’) will place a product outside the definition of a medical device. For example, at the 2014 Neurogaming conference, a panel of neurotechnology investors emphasized the importance of distinguishing between wellness and therapy claims for avoiding FDA regulation.⁷⁶ Indeed, many consumer EEG devices—which, as mentioned in the introduction, monitor rather than stimulate the brain’s activity—seem to have strategically marketed their devices for ‘improving mental fitness’ and ‘optimizing brain performance’.⁷⁷ However, it should be noted that the lack of formal enforcement action on the part of the FDA in the consumer neurotechnology arena (ie with regard to both tDCS and EEG devices) does not necessarily indicate that the FDA shares this view.

To address the regulatory status of health-related wearable technology devices, the FDA published a draft guidance on January 20, 2015, titled ‘General Wellness: Policy for Low Risk Devices’.⁷⁸ Although guidances are non-binding, the FDA has in recent years increasingly used them to reflect its latest thinking to industry. The draft guidance—which, it should be emphasized, is not the final version of the guidance, nor will it be binding or enforceable when it is finalized—indicates that the FDA does *not* intend to enforce device provisions for ‘general wellness products’ presenting a low risk to safety. The draft guidance defines a general wellness product in terms of intended use claims: a general wellness product is one that makes claims related to ‘maintaining or encouraging a general state of health’ without references to diseases or conditions. Among the examples of acceptable wellness claims provided are those relating to ‘mental acuity’, ‘concentration’, ‘problem-solving’, and ‘relaxation and stress management’.⁷⁹ Furthermore, the draft guidance indicates that even certain structure/function claims are permitted under the umbrella of ‘wellness claims’: examples of acceptable claims include those related to improving muscle size, toning the body, enhancing cardiac function, and improving sexual performance, among others.⁸⁰ Thus, at first glance, the draft guidance seems to indicate that the FDA does not intend to enforce regulations for tDCS devices marketed for wellness purposes.

However, the draft guidance also provides a second criterion: the product must be a low-risk device. According to the draft guidance, a product is *not* a low-risk device if ‘it involves an intervention or technology that may pose a risk to a user’s safety if device controls are not applied’.⁸¹ The draft guidance also states that in determining whether

⁷⁶ Neurogaming 2014, *Investing in Neurogaming: Panel Discussion*, May 7, 2014, video recording at <https://www.youtube.com/watch?v=fz95kEx3zx4>.

⁷⁷ See eg Muse, <http://www.choosemuse.com/>; Emotiv Insight, <https://emotiv.com/insight.php>; Neurosky, <http://neurosky.com/>; Melon <http://www.thinkmelon.com/>; and FocusBand <http://www.ifocusband.com/> (accessed March 2015).

⁷⁸ US Food And Drug Administration, *General Wellness: Policy for Low Risk Devices Draft Guidance for Industry and Food and Drug Administration Staff*, Jan. 20, 2015, <https://www.federalregister.gov/articles/2015/01/20/2015-00756/general-wellness-policy-for-low-risk-devices-draft-guidance-for-industry-and-food-and-drug> (accessed Mar. 1, 2015).

⁷⁹ *Id* at 3.

⁸⁰ *Id* at 4.

⁸¹ *Id* at 5.

a device is low risk, the manufacturer should consider whether a similar device is ‘actively regulated’ by the FDA. Though the guidance provides a number of examples of low-risk devices (mobile apps, wearable heart-rate monitors) and non-low-risk devices (cosmetic implants, laser technology products), electrical brain stimulation devices are not mentioned. Would consumer tDCS products be classified as low-risk devices? On the one hand, tDCS has been consistently shown to have relatively mild side effects (eg surface skin burns, headaches, and dizziness).⁸² On the other hand, no serious or chronic adverse events have been reported in the literature.⁸³

The recent letter from the FDA to Thync regarding the classification of its device supports the notion that the FDA does not view consumer neurotechnology devices that have intended uses related to wellness or recreation as medical devices. Prior to going to market, Thync submitted a 513(g), requesting information from the FDA regarding how it would classify its product.⁸⁴ According to the company, the FDA exempted the product from medical device requirements such as pre-market approval and clearance, as the product was intended for recreational purposes.⁸⁵ It should be noted, however, that the same decision might not hold true for manufacturers who do not limit their claims to recreational use. Furthermore, it is worth pointing out that the communication between the FDA and Thync has not been made public; all information regarding the FDA’s letter has come from the company itself.

Still, one question remains: if the definition of a medical device is based on its intended use—and neither on risk level nor mechanism of action—could a consumer device making only wellness or recreational claims (and not disease or medical-related structure/function ones) fall under the scope of FDA regulation? Furthermore, how can the draft guidance pose risk level as a criterion for regulation, if risk level only defines the regulatory process once a device is considered to be within the jurisdiction of the FDA? Answering these questions requires an examination of how courts have construed the FDA’s statutory authority with regard to medical devices, which is the topic of the next section.

III. Judicial interpretation of ‘intended use’ and medical devices

When determining the intended use of a product, the FDA has historically relied almost exclusively on manufacturers’ claims as represented on the product’s labeling and

⁸² Andre R Brunoni et al., *A Systematic Review on Reporting and Assessment of Adverse Effects Associated with Transcranial Direct Current Stimulation*, 14 INT. J. NEUROPSYCHOPHARMACOL. 1133 (2011).

⁸³ Fregni et al., *supra* note 7.

⁸⁴ Interview with Jamie Tyler, CEO of Thync (Feb. 12, 2015). The company submitted a 513(g) ‘Request for Information’ to the FDA, which is a ‘means of obtaining the agency’s views about the classification and the regulatory requirements’ applicable to a particular device. See US Food and Drug Administration, *Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act*, Apr. 6, 2012, <http://www.fda.gov/RegulatoryInformation/Guidances/ucm209841.htm> (accessed Feb. 26, 2015).

⁸⁵ The Thync press release accompanying the launch of its device included the following statement: ‘Based on its intended use in lifestyle applications, the FDA exempted the Thync System from medical device regulations requiring pre-market notification (clearance) or approval’. Thync Press Release, *Thync Launches First Wearable to Shift Your State of Mind, Consumer Product Delivers Calm and Energy within Minutes*, June 2, 2015, <http://www.thync.com/resources/press-release/thync-launches-first-wearable-to-shift-your-state-of-mind> (accessed June 12, 2015).

advertising.⁸⁶ For example, in two cases from the 1950s, district courts upheld the focus on marketing claims, finding that cigarettes making disease prevention⁸⁷ or weight-loss claims⁸⁸ came under the FDA's jurisdiction, whereas cigarettes that lacked such claims fell outside it. (Both of these cases came prior to the Medical Device Amendments of 1976, and the courts in each case considered the cigarettes to be drugs, not devices.) Indeed, today there are many 'dual use' products that are identical in technology but regulated differently based on intended use as represented by the manufacturer's intent. For example, exercise equipment marketed for medical purposes is regulated by the FDA,⁸⁹ but exercise equipment for recreational use is regulated by the Consumer Product Safety Commission (CPSC).⁹⁰ Other dual use products include bed rails,⁹¹ razors, and binoculars.⁹²

Though the FDA has focused almost exclusively on marketing language to establish intended use, a close read of 21 C.F.R. Section 801.4 ('meaning of intended uses') shows that the FDA can consider a variety of factors: intent may be shown by the 'circumstances surrounding the distribution of the article' or 'oral and written statements' by the manufacturers and their representatives.⁹³ Indeed, the courts have affirmed the FDA's extensive powers in this regard: in one case, the Seventh Circuit upheld the FDA's reliance on instruction booklets, financial arrangements, and individuals' testimonies in determining the intended use of a product.⁹⁴ In another, a district court agreed that the FDA could rely upon the 'circumstances surrounding the distribution of the article' to determine that a product was a drug, even in the absence of explicit labeling.⁹⁵ Furthermore, according to 21 C.F.R. Section 801.4, if the FDA can demonstrate that the 'article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised', it can deem the device misbranded.⁹⁶ With these broad criteria, the FDA would likely be well within its authority to take action against many small-scale tDCS manufacturers.

⁸⁶ For a comprehensive overview of intended use as it relates to medical devices, see Gary E. Gamerman, *Intended Use and Medical Devices: Distinguishing Nonmedical Devices from Medical Devices under 21 USC 321(h)*, 61 GEO. WASH. L. REV. 806 (1993). See also Hutt et al., *supra* note 51 at 92, 97.

⁸⁷ *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953).

⁸⁸ *United States v. 354 Bulk Cartons... Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959).

⁸⁹ See eg 21 C.F.R. §§ 890.5350–5410 (2015), defining various kinds of FDA-regulated exercise equipment as those 'intended for medical purposes'.

⁹⁰ See Part V for further discussion of the Consumer Product Safety Commission.

⁹¹ US Food and Drug Administration, *Bed Rail Safety: FDA and CPSC Activities*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362867.htm> (accessed Mar. 20, 2015).

⁹² Gamerman *supra* note 86 at 833, 835, and n.182.

⁹³ See *supra* note 66 for full text of 21 C.F.R. § 801.4.

⁹⁴ *United States v. An Article of Device... Toftness Radiation Detector*, 731 F.2d 1253, 1257 (7th Cir. 1984).

⁹⁵ The product was a unlabeled balloon filled with nitrous oxide, and the 'circumstances surrounding the distribution' were that the defendants were selling balloons outside a rock concert. The court found this information sufficient to establish intended use, and nitrous oxide was therefore considered a drug. *United States v. Travia*, 180 F. Supp. 2d 115 (D.D.C. 2001).

⁹⁶ See *supra* note 66 for full text of 21 C.F.R. § 801.4. This particular line has most notably applied to the off-label use of drugs: it is legal for physicians to prescribe a drug (or device) for an indication other than that for which it has been approved by the FDA, but a manufacturer cannot advertise, label, or otherwise represent the drug (or device) for a purpose other than approved by the FDA (21 C.F.R. § 801.4). This rule has been recently challenged on First Amendment grounds: for review see Stephanie M. Greene & Lars Noah, *Debate: Off-Label Drug Promotion and the First Amendment*, 62 U. PA. L. REV. 239, 267 (2014).

Even if a consumer tDCS device makes no explicit or implied medical-related claims, can the way that consumers actually use the product be sufficient to imply an intended use? This question has previously been raised in cases regarding cigarette regulation.⁹⁷ In the late 1970s, a citizen action group, Action on Smoking and Health (ASH), attempted to compel the FDA to regulate cigarettes, arguing that the way in which consumers actually used cigarettes demonstrated that the product's 'intended use' was to 'affect the structure or function of the body'.⁹⁸ The FDA refused to regulate, citing the absence of manufacturers' health claims.⁹⁹ In 1980's *Action on Smoking and Health (ASH) v. Harris*, the D.C. Circuit ruled that while it may be possible to demonstrate intention by showing actual consumer use, the standard was high, as it had to be shown that consumers were using a product 'nearly exclusively' for a given intention.¹⁰⁰ The court noted that 'ASH did not establish, and arguably cannot establish, the near-exclusivity of consumer use of cigarettes with the intent "to affect the structure or any function of the body of man..."'¹⁰¹ However, even if ASH had been able to demonstrate that consumers were indeed using cigarettes exclusively to affect the structure or function of the body, the court would have had to confront the question of whether the structure/function use had medical or therapeutic connotations. Exercise machines for recreational purposes, for example, are used by consumers 'nearly exclusively' to affect the structure or function of the body, yet they are not regulated as medical devices.

The question of whether the 'actual and foreseeable use' of cigarettes could be sufficient to demonstrate an intended structure/function use was raised again in 1995, when the FDA, under Commissioner David Kessler, attempted to regulate tobacco.¹⁰² The tobacco industry challenged the FDA, and the case ultimately went to the Supreme Court.¹⁰³ In *Food and Drug Administration v. Brown & Williamson* (2000), the Court rejected the FDA's assertion of jurisdiction over cigarettes but did not address the question of 'actual and foreseeable use' vs. 'intended use', and the matter has never been subsequently resolved in court.¹⁰⁴ However, it should be noted that in the 2002 letter from the FDA Chief Counsel mentioned in the previous section, the FDA took the position that '[f]oreseeability by the manufacturer does not suffice to establish intended use'.¹⁰⁵

Thus, intended use has most often been determined with relation to marketing claims (although the FDA is fully within its power to consider a broad range of factors) and 'actual or foreseeable use' has not been sufficient to determine intended use. While the FDA and courts have favored a narrow interpretation of 'intended use', recognizing that a literal reading of the structure/function definition would open up the door for

⁹⁷ For overview, see Margaret A. Boyd, *Butt Out!! Why the FDA Lacks Jurisdiction to Curb Smoking of Adolescents and Children*, 13 J. CONTEMP. HEALTH LAW POL'Y, 169 (1997). See also Hutt et al. *supra* note 51 at 139, 145 (on struggles over tobacco regulation).

⁹⁸ Hutt et al., *supra* note 51, at 140, and *infra* note 99.

⁹⁹ See history as set out in *Action on Smoking And Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

¹⁰⁰ *Id.* at 237.

¹⁰¹ *Id.*

¹⁰² Food and Drug Administration, 60 Fed. Reg. 41,314, (Aug. 11, 1995).

¹⁰³ Hutt et al., *supra* note 51, 140, 141.

¹⁰⁴ Food and Drug Administration v. Brown & Williamson Tobacco Corp. 529 U.S. 120 (2000). It was not until Congress passed the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA, Pub. L. No. 111-131) that tobacco came under the jurisdiction of the FDA.

¹⁰⁵ Troy, *supra* note 75, at 5.

a large number of consumer products to come under its jurisdiction, it is important to note that courts are often willing to give deference to the FDA's statutory interpretations. For example, in *United States v. An Article of Drug... Bacto-Unidisk (1969)*, the Supreme Court upheld the FDA's decision to classify an antibiotic sensitivity disc as a drug rather than a device, because doing so would subject the product to more stringent requirements.¹⁰⁶ The Court reasoned that Congress had not meant for the statute to be read narrowly: rather, the FD&C Act 'is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health'.¹⁰⁷ Subsequent opinions, such as the dissent in *Brown & Williamson*, have quoted this line when reasoning in favor of a liberal interpretation of the FD&C Act.¹⁰⁸ However, it is unlikely that a similar 'public health' argument could be made with regard to consumer tDCS, as it would have to be demonstrated that tDCS posed a significant public health risk—and according to one recent empirical study, the home use of tDCS 'does not seem to pose an imminent risk or danger to the public'.¹⁰⁹

Importantly, when attempting to both understand and predict the actions of the FDA, it should be emphasized that the agency does not act consistently over time; instead there is variation across different leaderships and agency actions. Thus, it is impossible to draw a single coherent picture of how the FDA (and courts) has acted. For example, in at least one instance, the FDA seemed to contradict its stance that structure/function claims must be medically related: in July 2000, it sent a warning letter to a company marketing a battery-powered facial mask called Rejuvenique, which applied electrical stimulation to the face. In the warning letter—which, it should be noted, is not final agency action—the FDA wrote that regardless of the manufacturers' claims, 'because the Rejuvenique is intended to affect the structure or function of the body by providing electrical current to various facial muscles to repeatedly contract them, it is a device...'.¹¹⁰ The company's lawyers responded with a 15-page letter, arguing that the product was not a medical device because the FDA classifies devices based on intended use, not mechanism of action.¹¹¹ Evidently, however, the company decided it was in their best interest to work with the FDA rather than litigating, because one year later the Rejuvenique was cleared via the 510(k) process.¹¹²

¹⁰⁶ *United States v. An Article of Drug... Bacto-Unidisk*, 394 U.S. 784 (1969). The case took place prior to the passage of the Medical Device Amendments, when devices, unlike drugs, did not have to undergo pre-market approval.

¹⁰⁷ *Id.* at 798.

¹⁰⁸ In his dissent, Justice Breyer argued that cigarettes should indeed be regulated by the FDA, because (a) the purpose of the FD&C Act is to protect public health; and (b) cigarettes are certainly intended to affect the structure or function of the body. *Food and Drug Administration v. Brown & Williamson Tobacco Corp.* 529 U.S. 120 (2000). (Breyer, J., dissenting).

¹⁰⁹ See *Jwa*, *supra* note 3 at 25.

¹¹⁰ Larry D. Spears for Steven D. Niedelman, Acting Director, Office of Compliance, Food and Drug Administration, *Warning Letter to Salton, Inc.*, July 12, 2000, <http://www.casewatch.org/fdawarning/prod/2000/salton.shtml> (accessed Mar. 15, 2015).

¹¹¹ Georgia C. Ravitz, Counsel for Salton, Inc., *Re: Rejuvenique Facial Toning System*, to Mr. William F. Defibaugh, Compliance Offer, Center for Devices and Radiological Health, Aug. 11, 2000, http://media.corporate-ir.net/media_files/nys/sfp/salton_rejuv.pdf (accessed Mar. 15, 2015).

¹¹² 510(k) Summary — Rejuvenique® Facial Toning System, Aug. 8, 2001, http://www.accessdata.fda.gov/cdrh_docs/pdf/k011935.pdf (accessed Feb. 25, 2015). Note, however, that this pathway was somewhat unusual because a 510(k) is granted when the device is similar in both 'intended use' and 'technological characteristics'. Here the intended use was cosmetic, not therapeutic.

The Rejuvenique case is particularly informative, as it exemplifies the typical negotiations between government agency and manufacturer following a warning letter. While the Rejuvenique manufacturer could have challenged the FDA in court, it chose the faster and cheaper option of working with the agency. Indeed, practical business considerations may be the best predictor of how a company will engage with the FDA. Many companies that have a product of unclear regulatory status—especially if they are investor backed or are looking for funding—will open a dialog with the FDA early in the development process, so as not to risk later regulatory action. Indeed, it is hard to imagine that venture capital-backed companies such as Thync and Halo Neuroscience would have been able to raise millions of dollars without a solid regulatory plan. (As noted in the previous section, Thync was in contact with the FDA prior to going to market;¹¹³ press mentions of Halo Neuroscience have indicated that the company intends to work with the agency.)¹¹⁴ By contrast, a small-scale tDCS consumer device manufacturer without the funds for legal counsel would probably attempt to place its device outside of the scope of FDA regulation. A manufacturer of this kind who received a warning letter or notice of violation from the FDA could in theory litigate (assuming that its product does not have an medical or disease-related intended use according to all the factors set out in 21 C.F.R. Section 801.4), but in practice it would not likely be worth the time or money. The section below illustrates what happened when the state of California—acting on an email from an engineer at the FDA—sent a notice of violation to a small-scale consumer tDCS manufacturer.

IV. Regulatory action to date—the CDPH and TDCS Device Kit, Inc.

Thus far, the only instance of regulatory enforcement against a consumer tDCS device has come at a state level, from the CDPH, which in May 2013 took action against a company called TDCS Device Kit, Inc., for violating California’s Sherman Food Drug, and Cosmetic Law.¹¹⁵ According to California state law, medical devices that are not federally approved for market in the United States can be considered misbranded and/or adulterated under the Sherman Law.¹¹⁶ Furthermore, the Sherman Law requires anyone manufacturing a medical device in California to obtain a license from the CDPH.¹¹⁷

According to the CDPH report, the investigation of TDCS Device Kit was initiated following receipt of an email and five-page analysis from a biomedical engineer at the FDA’s Center for Devices and Radiological Health.¹¹⁸ The company, which

¹¹³ Interview with William (Jamie) Tyler, co-founder and chief scientific officer (CSO) of Thync, Feb. 12, 2015.

¹¹⁴ Ben Popper, *The Halo Neuroscience Headband Wants to Make You Smarter by Shocking Your Brain*, THE VERGE, April 30, 2014, <http://www.theverge.com/2014/4/30/5668086/halo-neuroscience-brain-stimulation-funding-andressen> (accessed Feb. 25, 2015); John Biggs, *Halo, the Brain-Improving Wearable, Raises \$1.5 Million*, TECH CRUNCH, May 1, 2014, <http://techcrunch.com/2014/05/01/halo-the-brain-improving-wearable-raises-1-5-million/> (accessed Feb. 25, 2015).

¹¹⁵ State of California Department of Public Health, Food and Drug Branch, Medical Device Safety Unit, *Medical Device Investigative Report*, TDCS Device Kit, Inc., inspection date May 7, 2013.

¹¹⁶ Cal. HSC. Code § 109875 *et seq.* See also *infra* 143 and 144 and related text for a discussion of the overlap between federal and state medical device laws.

¹¹⁷ Cal. HSC. Code § 111615.

¹¹⁸ The engineer was in the Office of Device Evaluation/Division of Neurological and Physical Medicine Devices/Physical Medicine and Neurotherapeutic Devices Branch (CDRH/ODE/DNPM/NDNB); *supra* note 115.

was based in California, had been selling a 'Home TDCS Device Kit' via its website (www.tdcdevicekit.com). The FDA engineer had concluded that the 'Home TDCS Device Kit' was a Class III medical device and would require 510(k) clearance to be legally marketed in the USA, as the company's website implied that the device could be used to treat a variety of disorders. Although the company never explicitly claimed that its own device had medical benefits, its website did contain several paragraphs about tDCS, with sentences such as: 'Clinical therapy using TDCS may be the most promising application of this technique. There have been therapeutic effects shown in clinical trials involving Parkinson's disease, tinnitus, fibromyalgia, and post-stroke motor deficits'.

In May 2013, an investigator from the CDPH contacted the president of TDCS Device Kit, Richard O'Rourke, who believed that his product did not require CDPH clearance, since the product was a kit that was assembled by the user. A few days later, the same investigator met O'Rourke and inspected the manufacturing facility; the company was issued a notice of violation that day for non-compliance with California's Sherman Food, Drug and Cosmetic Law for manufacturing medical devices without a license from the CDPH.¹¹⁹ Two weeks later, the CDPH issued TDCS Device Kit a second notice of violation, this time with 11 items related to 'selling and delivering misbranded, adulterated, and unapproved medical devices'. According to the notice of violation, the device was unapproved by the FDA; it was adulterated in that it did not comply with good manufacturing practices and performance standards; and it was misbranded in that the manufacturing establishment was not licensed by the FDA or the CDPH, and the label failed to bear adequate warnings, directions, and other information.¹²⁰

The company subsequently stopped selling the devices, and a sentence was added to its website, noting that the kits were 'unavailable at this time'. O'Rourke, however, was reluctant to issue a recall, and evidently did not take action to meet with the FDA or medical device regulatory counsel to negotiate a plan to secure approval for the device. Therefore, the CDPH moved forward, issuing a press release on June 28, 2013, titled 'CDPH Warns Consumers Not to Use TDCS Home Device Kit'.¹²¹ The next month, TDCS Device Kit sent out a recall email to over 200 customers. The investigation was officially closed in October 2013, following a CDPH determination that the firm's recall efforts were adequate.¹²²

There are several contextual points of interest in this case. First, it remains an open question why the FDA engineer conducted his or her own analysis, yet forwarded the issue to the CDPH. One possibility is that the FDA engineer did not have evidence of the product being sold across state lines; the FDA's jurisdiction lies only in interstate commerce, not in intrastate commerce.¹²³ Another possibility is that it was simpler to hand the case off to the state and not engender complex federal regulatory processes.

¹¹⁹ *Supra* note 117.

¹²⁰ *Supra* note 115.

¹²¹ California Department of Public Health, *CDPH Warns Consumers Not to Use TDCS Home Device Kit*, June 28, 2013, <http://www.cdph.ca.gov/Pages/NR13-029.aspx> (accessed Feb. 1, 2015).

¹²² State of California Department of Public Health, Food and Drug Branch, Medical Device Safety Unit, *Medical Device Investigative Report*, TDCS Device Kit, Inc., inspection date Oct. 7, 2013.

¹²³ *Infra* note 144.

In response to a query regarding the frequency of FDA referrals for medical device investigations, the CDPH noted that such referrals occur ‘occasionally’.¹²⁴

Second, all items in the 11-item notice of violation referred to the device as a ‘*prescription* medical device’ (emphasis added). The fifth item on the notice of violation was based entirely on this characterization, stating that the device was misbranded because the label failed to bear the statement ‘Caution: federal law prohibits dispensing without a prescription...’ or similar language. However, there is no clinical use of tDCS that is FDA approved, either for prescription or over-the-counter use. When queried about the use of the term, the CDPH noted that when ‘additional information was obtained, it was determined the product was an unapproved new medical device as opposed to a prescription medical device’.¹²⁵ Indeed, the second, shorter CDPH report does not mention the word ‘prescription’, but it also does not make note of the initial error.

Third, even though TDCS Device Kit never made a specific disease or structure/function claim for its product, the report states that treatment claims were ‘implied’ by the website. Thus, if statements about the clinical effects of tDCS appear on a website that sells a consumer tDCS device, representatives from the FDA and the state of California have inferred that the product is a medical device. Furthermore, designing and marketing a consumer tDCS device as a ‘kit’ made no meaningful difference. Thus, several manufacturers that currently sell consumer tDCS devices may be liable to receive notices of violation (at the state or federal level) for unapproved, adulterated, or misbranded medical devices. As noted in Part II, several manufacturers link to, or mention, research regarding the therapeutic effects of tDCS.

Fourth, according to the CDPH report, the FDA engineer’s five-page analysis concluded that the device was a Class III device that would require a 510(k) clearance before marketing. This implies that the FDA engineer had characterized the device as substantially equivalent to an existing pre-amendment Class III device, which as mentioned in Part II, is a device that poses the highest risk of injury and illness. The existing Class III device most similar to tDCS is a CES device, which according to the FDA’s definition, ‘applies electrical current to a patient’s head to treat insomnia, depression, or anxiety’.¹²⁶ The main difference between the two is that while tDCS uses direct current, CES uses alternating current.¹²⁷ The assumption of substantial equivalence to CES would explain the CDPH report’s (incorrect) observation that tDCS ‘is typically used to treat depression and other mood disorders’. It would also explain the use of the term ‘prescription’ in the CDPH’s violation notice, as CES is currently a prescription-only device.

¹²⁴ E-mail from Ronald Owens, Office of Public Affairs, California Department of Health, to Anna Wexler (Feb. 13, 2015), on file with author.

¹²⁵ E-mail from Ronald Owens, Office of Public Affairs, California Department of Health, to Anna Wexler (Feb. 2, 2015), on file with author.

¹²⁶ 21 C.F.R. § 882.5800 (2015).

¹²⁷ Although the FDA’s definition of CES is broad, the agency has elsewhere described the specific characteristics of CES and has distinguished it from tDCS. See eg, Section 1.2 in US Food and Drug Administration, FDA Executive Summary: Prepared for the February 10, 2012 meeting of the Neurologic Devices Panel, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/UCM290787.pdf> (accessed Sep. 22, 2015).

The comparison of tDCS to CES is especially interesting in light of the ongoing battles about whether CES should be categorized as a Class II or Class III device. As mentioned earlier, the vast majority of non-invasive electrical stimulation devices for medical purposes are categorized as Class II devices, and CES manufacturers have long attempted to have the CES device reclassified from a Class III to Class II. In recent years, however, the FDA has tried unsuccessfully, and against heavy resistance, to increase the burden on CES manufacturers.¹²⁸ In June 2014, in response to a flood of public comments, the FDA stated that it planned to reclassify the device as Class II, although it has yet to follow through with this reclassification.¹²⁹ It is likely that the particular CES troubles are a consequence of being grandfathered in under the 1976 Medical Device Amendments and automatically categorized as a Class III device; CES was therefore never required to submit a PMA demonstrating safety and efficacy. The lack of PMA for CES also explains the FDA engineer's surprising determination that the 'Home tDCS Device Kit' was substantially equivalent to an existing Class III device and would require 510(k) clearance, as most new Class III devices cannot be cleared via the 510(k) process. The engineer likely had CES in mind, because the only instance where a new Class III device can be cleared via the 510(k) process is if it can demonstrate substantial equivalence to a 'preamendment' device that was automatically classified as Class III, such as CES.¹³⁰

In sum, the CDPH case shows that contrary to common perception, the FDA has been involved in the regulation of consumer tDCS devices; however, it should be emphasized that the FDA engineer's email and analysis does not represent the formal position of the FDA.¹³¹ Though there was initial uncertainty on the part of the CDPH regarding the status of consumer tDCS devices, state and federal regulators still considered the product to be a medical device based on manufacturer's statements about the therapeutic effects of tDCS. Importantly, the use of the term 'kit' did not offer any protection. Finally, the only documented case to date of the FDA's involvement in tDCS indicates that at least one engineer in its offices has viewed tDCS for medical purposes as a Class III device. While this will likely be surprising for researchers who have

¹²⁸ In 2011, the FDA issued a proposed rule to require the filing of a PMA (or a notice of completion of a product development protocol, PDP) for CES devices. In response, three petitions were filed by CES manufacturers, requesting reclassification of CES devices into Class II. The petitions were referred to a 2012 Neurological Device Panel, which agreed that the devices should require PMAs and remain in Class III. In April 2013 (around the time the FDA emailed the CDPH), the FDA issued an order to require additional pre-market approval for CES devices. See Background section, US Food and Drug Administration, Neurological Devices; *Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Devices*, 79 Fed. Reg. 33,712 (June 12, 2014), to be codified at 21 C.F.R. 882.

¹²⁹ *Id.*

¹³⁰ See *infra* note 63.

¹³¹ Under 21 C.F.R. 10.85(k), a statement by an FDA employee represents only the best personal judgment of that individual and 'does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed'. 21 C.F.R. 10.85(k), <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=10.85> (accessed Jan. 25, 2015).

assumed that tDCS for medical use would be a Class II device, the report should be taken with a grain of salt, as the FDA engineer's analysis is not representative of the agency's formal position. Indeed, another device similar to tDCS—one that provides electrical stimulation to the head for headache treatment—was recently classified by the FDA as a Class II device.¹³²

V. Safety and advertising regulations for consumer products

If the FDA does not recognize consumer tDCS devices as medical devices (or opts not to enforce existing regulations), such products would still be subject to a multitude of consumer product safety and advertising laws. For example, the Federal Trade Commission (FTC) has the authority to take relevant administrative action for 'unfair or deceptive' business practices.¹³³ The FTC interprets the term 'deceptive' broadly—to include 'sales of hazardous... products... without adequate disclosures'—and therefore issues related to the sale of consumer tDCS products could fall under its scope.¹³⁴ While the FTC regulates the advertising of consumer products as well as over-the-counter drugs and medical devices, the FDA maintains regulatory authority over the advertising of restricted (ie prescription) drugs and medical devices, and for the labeling of all products under its jurisdiction.¹³⁵ Thus, if the FDA classifies consumer tDCS products as *unrestricted* medical devices, oversight of their advertising would fall under the FTC and labeling under the FDA; if such devices are considered consumer products, oversight of both advertising and labeling would fall under the broad brush of the FTC. Two recent FDA guidances—the wellness device draft guidance mentioned in Part II and a 2015 guidance regarding health-related mobile applications—seem to shift a regulatory burden to the FTC by placing a large class of wellness products outside the scope of FDA regulation.¹³⁶ Indeed, the FTC recently filed a complaint against a company marketing a computer game that claimed to improve cognition in children.¹³⁷ It

¹³² US Food and Drug Administration, *Medical Devices; Neurological Devices; Classification of the Transcutaneous Electrical Nerve Stimulator to Treat Headache*, 79 Fed. Reg. 37,946 (July 3, 2014) to be codified at 21 C.F.R. 882, <https://www.federalregister.gov/articles/2014/07/03/2014-15625/medical-devices-neurological-devices-classification-of-the-transcutaneous-electrical-nerve> (accessed Feb. 22, 2015).

¹³³ 15 U.S.C. § 45(a)(1) (2012).

¹³⁴ Federal Trade Commission, *FTC Policy Statement on Deception*, <http://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception> (accessed Jan. 25, 2015).

¹³⁵ Although the FDA and FTC have overlapping jurisdiction, since 1954 they have operated under a Memorandum of Understanding. However, it should be noted that the Memorandum is only an informal division of authority. Working Agreement Between Federal Trade Commission and Food and Drug Administration, 36 Fed. Reg. 18,539 (Sept. 16, 1971), <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm> (accessed Jan. 20, 2015). See also discussion in James Serafino, *Developing Standards for Health Claims—The FDA and the FTC*, 47 FOOD & DRUG L.J. 335, 335–337 (1992).

¹³⁶ US Food and Drug Administration, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (Feb. 9, 2015), <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf> (accessed Feb. 22, 2015).

¹³⁷ Federal Trade Commission, Press Release, *Makers of Jungle Rangers Computer Game for Kids Settle FTC Charges that They Deceived Consumers with Baseless 'Brain Training' Claims*, Jan. 20, 2015, <http://www.ftc.gov/news-events/press-releases/2015/01/makers-jungle-rangers-computer-game-kids-settle-ftc-charges-the> (accessed Feb. 26, 2015).

also has pursued action against various mobile medical health apps in recent years, such as ones that have claimed to treat acne and diagnose melanoma.¹³⁸

With regard to safety, the CPSC is tasked with protecting the public from ‘unreasonable risks of injury associated with consumer products’,¹³⁹ and regulates products such as table saws, cribs, and carbon monoxide detectors. The CPSC has the authority to ban products, develop safety standards, and facilitate product recalls. All medical devices (and other products regulated by the FDA) fall outside the scope of the CPSC.¹⁴⁰ It should be noted, however, that as a matter of practice, some authorities may be reluctant to take enforcement action over a product that may fall under the primary jurisdiction of another agency. For example, if a product has the appearance of a medical device, an agency such as the CPSC may be hesitant to assert jurisdiction.

Another federal agency, the FCC, regulates the radio frequency output of various wireless technology devices, ensuring that they meet certain standards. While most tDCS devices from small-scale vendors do not incorporate wireless technology, both the Foc.us and the Thync devices have FCC certification, as they can be controlled wirelessly from a smartphone.¹⁴¹ The FCC and the FDA in some cases have overlapping jurisdiction, as they both regulate radiation-emitting products. For example, the FCC certifies cell phones and ensures that they meet certain radio frequency standards, whereas the FDA is responsible for potential cell phone-related health issues.¹⁴²

In addition to federal regulations, individual states also have health, safety, and medical device laws. According to section 521 of the FD&C Act, the FDA’s medical device regulations preempt (ie supersede) state laws.¹⁴³ Though the overlap between federal and state regulations is complex, in general, a state law cannot interfere with FDA regulations (eg it cannot set lesser criteria for what constitutes a medical device). However, in some cases a state can apply additional rules or more stringent requirements. For example, the first notice of violation issued to TDCS Device Kit was related to a state requirement (lack of licensing from the CDPH), not a federal one. Furthermore,

¹³⁸ Federal Trade Commission, Press Release, ‘Acne Cure’ Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements, Sept. 8, 2011, <https://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under> (accessed Jan. 8, 2015); and Federal Trade Commission, Press Release, *FTC Cracks Down on Marketers of ‘Melanoma Detection’ Apps*, Feb. 23, 2015, <https://www.ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps> (accessed Mar. 1, 2015).

¹³⁹ Consumer Product Safety Act (Codified at 15 U.S.C. §§ 2051–2089).

¹⁴⁰ US Consumer Product Safety Commission, *Products Under the Jurisdiction of Other Federal Agencies*, <http://www.cpsc.gov/en/Regulations-Laws-Standards/Products-Outside-CPSCs-Jurisdiction/> (accessed Jan. 25, 2015).

¹⁴¹ The application for FCC certification for the Foc.us devices (submitted by European Engineers Limited, FCC ID: 2AAH6DLIG1) and for the Thync device (FCC ID: 2AELZ-1000) are publicly viewable via an ‘Equipment Authorization Search’ on the FCC website: <https://apps.fcc.gov/oetcf/eas/reports/GenericSearch.cfm> (accessed Jan. 8, 2015).

¹⁴² US Food and Drug Administration, *Radiation-Emitting Products - Cell Phones*, <http://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/homebusinessandentertainment/cellphones/default.htm> (accessed Jan. 25, 2015).

¹⁴³ Section 521(a) of FD&C act, as codified in 21 C.F.R. § 808. For discussion, see Hutt et al., *supra* note 51 at 1280, 1282.

the FDA has jurisdiction only over interstate commerce, not intrastate commerce.¹⁴⁴ Currently, all US-based consumer tDCS device manufacturers are selling their products on an interstate level, but if every part of a device were to be manufactured and sold entirely within a single state—which, of course, is highly unlikely—the product would fall under state, and not FDA, jurisdiction. States also have their own consumer protection laws (often for unfair or deceptive business practices) that would be applicable in the realm of consumer tDCS.

With regard to the importation of foreign tDCS devices into the USA (such as those from the Hong Kong-based companies TCT Research Limited and PriorMind, both of which make explicit medical claims), the FDA imposes identical requirements on both foreign and domestic devices.¹⁴⁵ The FDA works with the Department of Homeland Security to inspect food, drugs, cosmetics, and medical devices, and the government has broad powers to detain or seize imports.¹⁴⁶ However, the FDA recognizes that it is not practical to inspect every item imported into the USA, and the agency has therefore been permissive with small quantities of drugs or devices imported for personal use. According to the FDA's Regulatory Procedures Manual, the agency exercises enforcement discretion even for items that are in clear violation of FDA regulations. However, the manual notes that although the FDA 'may use discretion to allow admission of certain violative items, this should *not* be interpreted as a license to individuals to bring in such shipments'.¹⁴⁷ The FDA is more likely to take enforcement action when the product presents a health risk, if it is being actively promoted to US customers, or if it is being shipped repeatedly and/or in large quantities.

Finally, the Better Business Bureau (BBB), a non-profit non-governmental organization, plays a major role in what it is referred to as industry 'self-regulation'.¹⁴⁸ The BBB interfaces between companies and consumers to settle complaints outside of court; it has already helped one consumer with a complaint about the Foc.us device.¹⁴⁹ The BBB also has a National Advertising Division, which monitors companies' advertising claims and attempts to resolve matters through settlements.¹⁵⁰ Thus, even if consumer tDCS devices are not regulated as medical devices by the FDA, they would still be subject to numerous federal and state consumer product laws.

¹⁴⁴ Section 301 of the FD&C Act.

¹⁴⁵ Section 801(a) of the FD&C Act.

¹⁴⁶ See Hutt et al., *supra* note 51 at 1450 for discussion of different outcomes for seizure as compared to refusal of admission.

¹⁴⁷ US Food and Drug Administration, Regulatory Procedures Manual, 9–2, Coverage of Personal Importations, <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm> (accessed Jan. 10, 2015).

¹⁴⁸ Council of Better Business Bureaus, Mission and Vision, <http://www.bbb.org/council/about/vision-mission-and-values/> (accessed Jan. 15, 2015); FTC Commissioner Maureen K. Ohlhausen has defined self-regulation as a 'broad concept that includes any attempt by an industry to moderate its conduct with the intent of improving marketplace behavior for the ultimate benefit of consumers'. Maureen K. Ohlhausen, *Remarks at the BBB Self-Regulation Conference*, June 24, 2014, at 2, http://www.ftc.gov/system/files/documents/public_statements/410391/140624bbbself-regulation.pdf (accessed Jan. 10, 2015).

¹⁴⁹ BBB Business Review, *European Engineers Limited* (see 'Complaint Resolution Log') <http://www.bbb.org/greater-san-francisco/business-reviews/home-electronics/european-engineers-limited-in-redwood-city-ca-459140/complaints> (accessed Jan. 25, 2015).

¹⁵⁰ National Advertising Division, <http://www.bbb.org/council/the-national-partner-program/national-advertising-review-services/national-advertising-division/> (accessed Jan. 25, 2015).

CONCLUSION

In sum, this paper has offered an in-depth, fact-based perspective on the regulation of consumer tDCS devices in the United States. Rather than a ‘regulatory gap’, there are multiple, distinct pathways by which consumer tDCS devices can be regulated in the United States. An examination of the existing consumer device market illustrated the complex array of various tDCS devices and the shift from DIY devices to DTC ones. A review of the statutory language of the FD&C Act as well as related judicial and agency interpretations demonstrated the importance of considering the precise language of the law (and the intended use claims made for each consumer tDCS device) as well as how the courts have construed the FDA’s authority. Although it is unclear whether the FDA or states will attempt to assert jurisdiction over small-scale consumer tDCS manufacturers, if regulatory action is initiated, such small-scale manufacturers may be able to challenge the FDA in limited circumstances,¹⁵¹ though in practice this is unlikely to be a successful or worthwhile endeavor. In addition, an analysis of the state regulatory action taken against TDCS Device Kit revealed one FDA engineer’s interpretation that a consumer tDCS product was a Class III device; it also provided an indication of the level of scrutiny that states and federal bodies might adopt in determining what constitutes an ‘implied’ therapeutic use claim. Finally, I have shown that if the FDA does not regulate consumer tDCS products as medical devices, such products would still be subject to a multitude of consumer safety and advertising regulations, although enforcement may not be vigorous.

Taken together, existing authorities provide diverse regulatory options. For example, products such as the Foc.us and tDCS device kits could be regulated as consumer devices, and therefore would be subject to the consumer safety and advertising laws outlined in the previous section. Foreign device manufacturers who ship consumer tDCS devices to the USA (such as TCT Research Limited and PriorMind) might not encounter regulatory issues if they ship in limited quantities to individuals for personal use. Companies with greater resources, such as Thync and Halo Neuroscience, may be more likely to work with the FDA; as mentioned above, according to Thync’s press release, the FDA exempted the company from obtaining approval or clearance for its device.

Separate from consumer tDCS devices, medical and investigational devices have their own regulatory pathways. Neuroconn could continue to provide its tDCS device to clinicians and researchers for investigational purposes only, under the FDA’s investigational device exemption. Scientists could continue to repurpose iontophoresis devices for use in research studies as long as such devices are deemed to be non-significant risk devices by their local Institutional Review Board. With regard to treatment, psychiatrists and other medical professionals could continue to repurpose iontophoresis devices for ‘off-label’ use for either cognitive enhancement or treatment; such a practice is legal in the United States.¹⁵² In the future, a company could demonstrate the safety and efficacy of its device for a specific clinical use (eg depression) and

¹⁵¹ Since 21 C.F.R. Section 801.4 allows the FDA to consider a broad range of factors in determining intended use, I use ‘limited circumstances’ here to refer to a situation wherein a disease claim or medical-related structure/function claim could not be construed based on all the factors set out in that section.

¹⁵² See *supra* note 96.

see it approved or cleared as a prescription-only medical device. Thus, while all of the above-mentioned examples involve some form of tDCS, each is subject to different forms of oversight.

Given the multitude of regulation covering various forms of tDCS devices, it is unclear how additional regulation might fit into the picture. Indeed, as I mentioned at the outset, many scholars have conflated the lack of enforcement with the lack of regulation. Furthermore, much of the existing literature has neglected to consider current legal frameworks and factors such as the practical feasibility of implementation (ie the procedures, costs, and length of time required to modify regulation), the precise targets of regulation (exactly which devices additional regulation would affect, and how), and possible social implications (such as the possibility that home users might go further ‘underground’ in response to a regulatory push). Indeed, modifying a regulatory framework to questionably encompass a small sliver of devices that have yet to cause any serious adverse effects seems both impractical and unrealistic.

Rather than focusing on the enforcement of existing regulation¹⁵³—which would not affect the use of home-built devices, the Thync device and iontophoresis devices—a more productive method might be to begin with a review of existing devices and the populations who use them, outlining the relevant issues of concern surrounding consumer non-invasive brain stimulation. While there has been a large body of literature on the ethics of cognitive enhancement drugs (eg inequality with regard to distribution, compelled use), the bulk of the conversation surrounding consumer tDCS devices has focused on issues of safety and risk. However, further clarification is necessary when using these terms, as even a device that complies with regulatory standards may not be ‘safe’ under certain usage practices (eg long-term use of the Thync device); whereas a device that does not meet technical output standards may be safe when used in a specific manner (eg a ‘DIYer’ using a home-built device). In other words, *who* is using the device is just as important as *what* device they are using. Furthermore, it is crucial to differentiate between short-term safety issues (eg side effects such as skin irritation and headaches) and long-term unknowns (eg the possibility of deleterious cognitive effects).

Importantly, the review could focus on establishing guidelines that address usage practices, rather than devices themselves. Such guidelines, which would be along the lines of the engagement approach that has been previously suggested in the literature,¹⁵⁴ could target home users, the general public, and physicians who currently administer tDCS for off-label use. Guidelines could reflect best usage practices, as well as current unknowns in the literature, and leave it to the users to make informed decisions. Such an approach could be quickly implemented, flexible, and would reach a global audience, rather than being limited to a specific country. Indeed, qualitative

¹⁵³ In most cases, a federal or state agency cannot be compelled to enforce existing regulation. However, complaints may be filed with the various regulatory authorities.

¹⁵⁴ See Fitz & Reiner, *supra* note 14, and Nicholas S. Fitz & Peter B. Reiner, *Buttressing Regulation of Cognitive Enhancement Devices with Principles of Harm Reduction*, 1 J. L. BIOSCI. 322 (2014).

studies have shown that tDCS home users look to the scientific community for guidance¹⁵⁵ and would be open to guidelines from researchers.¹⁵⁶

Though an engagement approach to the regulatory issues surrounding DIY tDCS was first proposed two years ago, as of yet, no initiative has come to fruition. Indeed, there are a number of practical barriers that should be acknowledged. First, as home users are perceived as ‘fringe’ or ‘unorthodox’ by much of the scientific community, there is likely a stigma attached to engaging with them directly. Second, given that tDCS is still very much in research and investigational stages, most scientists are probably unwilling to make proclamations about what is safe and what is not, and would likely not want to take steps that may be perceived as encouraging unsupervised use. Third, guidelines could lead to liability issues (eg if a home user injured himself despite following the guidelines). Fourth, given the lack of consensus within the tDCS field itself (eg with regard to optimal dosage and potential long-term deleterious effects), it may be difficult for researchers to agree on a single set of guidelines.

Given these obstacles, it may be beneficial for such guidelines to be developed under the umbrella of a reputable third party, such as the National Academy of Medicine (formerly known as the Institute of Medicine) or a neuroethics committee. A third-party might alleviate some of the stigma of interacting directly with the home users, and protections could be put into place to shield individual researchers from liability issues. Rather than reflecting a single consensus, guidelines could summarize the latest research regarding the short- and long-term issues regarding tDCS, with a focus on minimizing side effects and encouraging safe usage practices. Importantly, the committee could be an avenue not just for one-way communication from researchers to home users and the general public, but a venue for representatives of various groups to interact. Qualitative and quantitative work should continue to track tDCS home use and its potential uptake by the general public, in order to provide ongoing information regarding the use of non-invasive brain stimulation outside of academic settings.

Looking ahead, it is clear that electrical brain stimulation will soon become available to a larger audience than it ever has before. If Thync’s initial results are borne out—and its device does have the same effect as a glass of wine or a cup of coffee—then the technology could be profoundly transformative in ways that we cannot yet grasp. 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. Establishing a forum for the continued interaction among manufacturers, home users, and regulators would represent an important first step in this direction.

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¹⁵⁵ See Wexler, *supra* note 15.

¹⁵⁶ See Jwa, *supra* note 3.