What lies ahead for FDA regulation of tDCS products?

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In ‘A Pragmatic Analysis of the Regulation of Consumer tDCS Devices in the United States’, Anna Wexler examines how US laws apply to transcranial direct current stimulation (tDCS) products—products that provide a low level of electrical current to the brain.¹ How to regulate tDCS products is an interesting question in part because they are marketed directly to consumers both for treating sick patients and for promoting wellness or enhancing mental function in healthy individuals (Wexler calls this latter group ‘consumer’ products). Contrary to others’ concerns that consumer tDCS products fall into a ‘regulatory gap’, Wexler argues that there currently exists the potential for comprehensive US regulation if extant laws are enforced.

Unsurprisingly, Wexler identifies the U.S. Food and Drug Administration (FDA) as one possible regulator. After questioning FDA’s authority to regulate consumer tDCS products, Wexler concludes that FDA can oversee these products in many, but not all, circumstances.² My view is that there is a stronger case for FDA jurisdiction over a broader range of consumer tDCS products than Wexler’s article suggests. This view does not reflect any true disagreement with Wexler. Rather my optimism about FDA’s authority strengthens her central claim that there is no regulatory gap. Although FDA is not the only agency that may have jurisdiction over consumer tDCS products, FDA authority would significantly bolster—and might be necessary for—the argument that a comprehensive regulatory framework presently exists.

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² Id. at 677–87, 694.
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For FDA to regulate a consumer tDCS product, the product must meet the legal definition of a device, which the Federal Food, Drug, and Cosmetic Act defines as an ‘article’ that, among other things, is intended ‘for use... in the cure, mitigation, treatment, or prevention of disease’ or ‘to affect the structure or any function of the body’. Thus, as Wexler rightly explains, FDA’s authority to regulate a consumer tDCS product depends on whether the manufacturer represents it as treating a disease or affecting the body’s structure or function. Although each manufacturer’s representations must be assessed individually, my view is that manufacturers’ wellness and enhancement claims are generally claims that consumer tDCS products affect the structure or function of the body (structure/function claims). Certain statements may also be implicit claims that tDCS products cure, mitigate, treat, or prevent disease (disease claims).

One reason for my position is that many of the wellness and enhancement claims about tDCS products that seem to give Wexler and others pause are indistinguishable from statements that FDA has long publicly identified as disease or structure/function claims in other product areas. The following three examples illustrate this point. First, some in the neurogaming industry have asserted that ‘sleep aid’ and ‘supports sleep’ are claims that would place a product outside the device definition and FDA jurisdiction. But FDA described such statements as structure/function claims in a 2000 final rule regarding dietary supplements, and there appears to be little doubt within the supplement industry that these are structure/function claims. For products marketed as dietary supplements, the legal issue is typically whether a particular statement is a disease or structure/function claim because disease claims generally subject products to the more rigorous drug regulatory scheme. But FDA’s position on what constitutes a structure/function claim about a supplement is instructive—it is difficult to identify a principled reason that would support FDA categorizing such claims differently for tDCS products. Moreover, statements like ‘sleep aid’ may be disease claims if, in context, they imply that a product treats insomnia.

3 FDA jurisdiction is also tied to certain prohibited acts and the product’s movement in interstate commerce, which may thwart FDA oversight of do-it-yourself (DIY) tDCS products. But DIY products are beyond the scope of this response. 21 U.S.C. § 331 (2015); see also Anita Jwa, Adopters of The Magical Thinking Cap: A Study on Do-It-Yourself (DIY) Transcranial Direct Current Stimulation User Community, 2 J. L. & BIOSCI. 292, 320 (2015).


5 A device’s intended use is determined by the ‘objective intent of the persons legally responsible for the labeling,’ who I refer to as the manufacturer for simplicity. 21 C.F.R. § 801.4 (2016).


8 See 21 U.S.C. §§ 321(g), (f); 343(r)(6).

9 See Supplement Rule, 65 Fed. Reg. at 1022, 1031; Letter from John B. Foret, FDA, to Corey Resnick, Integrative Therapeutics, Inc. (Apr. 9, 2002), http://www.fda.gov/ohrms/dockets/dailys/02/Apr02/041702/97s-0163.Lett0581.vol17.pdf (identifying ‘Natural Sleep Aid’ as a disease claim); cf. United States v. 23, More or Less, Articles, 192 F.2d 308 (2d Cir. 1951) (concluding phonograph records marketed with claims like ‘Sleep Guaranteed’ were devices).
As a second example, claims about tDCS products’ enhancement effects—such as ‘make your synapses fire faster’, ‘charge your mind’, and ‘increase your attention span’—are generally structure/function claims. These statements explicitly (e.g. ‘make your synapses fire faster’) or implicitly (e.g. ‘charge your mind’) assert that tDCS products stimulate brain structures or support or enhance cognitive function. And claims about tDCS products improving cognitive function may also be disease claims.\(^\text{10}\) For instance, in some circumstances ‘increase your attention span’ may imply treatment of attention deficit hyperactivity disorder (ADHD) because a short attention span is a well-known symptom of ADHD.

As a final example, even the consumer tDCS product sold by Super Specific Devices, the manufacturer that Wexler identifies as making no claims, is likely a device within FDA jurisdiction. Super Specific Devices’ website does make claims—albeit vague ones—about its ‘personal tDCS device’. The user reviews webpage discusses ‘treatment’, and the directions webpage instructs customers to record how the product affects them, including ‘immediate sensations’ like ‘stinging and redness’.\(^\text{11}\) The directions webpage also ‘recommends’ and links to an external webpage that provides instructions on how to place the product’s electrodes to achieve various functional and treatment outcomes, such as ‘enhancing motor ability and reducing pain’.\(^\text{12}\) Collectively these facts suggest that Super Specific Devices intends its product to affect the body’s structure or function or treat disease.

That tDCS products are thought to affect cognitive function might be additional evidence of the intended use of Super Specific Devices’ product. In a 2010 warning letter to the distributor of ‘Magic Power Coffee’, FDA made such an argument.\(^\text{13}\) In that warning letter, FDA asserted that Magic Power Coffee was intended for disease treatment or to affect the body’s structure or function because of claims like ‘for best results use approximately 30–45 min prior to engaging in sexual intercourse’, and because the product contained an analog of the active ingredient in Viagra, which is well-known to affect sexual function.\(^\text{14}\) Warning letters are not final agency action, nor are they general policy statements. Additionally, the evidence suggesting that tDCS products affect the body is likely not as robust as the evidence for Viagra. Nevertheless, the Magic Power

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\(^\text{10}\) See eg Supplement Rule, 65 Fed. Reg. at 1006; see also United States v. Article or Device . . . ‘Hubbard Electrometer,’ 333 F. Supp. 357 (D.D.C. 1971) (concluding scientology ‘E-meters’ were devices based on claims to ‘improve[] . . . health, intelligence, ability . . . skill’).


\(^\text{13}\) See Warning Letter from Ronald M. Pace, FDA to Peter Erlikh, INZ Distributors, Inc. (Aug. 23, 2010), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm225432.htm [hereinafter ‘Magic Power Coffee Warning Letter’]. Additionally, in a 2000 warning letter to the manufacturer of ‘Rejuvenique’, FDA cited as evidence of intended use both the manufacturer’s claims and Rejuvenique’s physiologic effect. As Wexler explains, FDA also stated that Rejuvenique would be a device ‘even if no claims were made for its specific use’ because of how the product functioned. Warning Letter from Larry D. Spears, FDA to Salton, Inc. (July 12, 2000) http://www.casewatch.org/fdawarning/prod/2000/salton.shtml. FDA, however, does not need to take that position to reach Super Specific Devices’ product.

\(^\text{14}\) See Magic Power Coffee Warning Letter; see also United States v. Travia, 180 F. Supp. 2d 115 (D.D.C. 2001) (concluding nitrous oxide was a drug in the absence of any labeling, based on the ‘totality of the circumstances’); Supplement Rule, 65 Fed. Reg. at 1006 (‘FDA’s longstanding interpretation of [the Federal Food, Drug, and Cosmetic Act] authorizes the agency to rely on evidence outside the labeling and advertising of a product to establish its intended use’).
Coffee warning letter suggests that there is sufficient evidence of intended use for FDA to regulate Super Specific Devices’ product. And together, the above examples indicate that it would be consistent with FDA’s positions in other product areas to conclude that many claims about tDCS products are disease or structure/function claims.15

Wexler argues that in some instances courts have confined FDA’s jurisdiction over products marketed with structure/function claims to those that have a ‘therapeutic connotation’, which may limit FDA’s ability to regulate consumer tDCS products.16 And FDA itself has applied commonsense limits to the scope of its jurisdiction because construing structure/function claims as broadly as possible would give FDA authority over an incredible range of products, including all exercise equipment.17 But a commonsense limit on structure/function claims or a judicially created requirement for a therapeutic implication should not pose serious obstacles to FDA asserting jurisdiction over consumer tDCS products. The courts that arguably have limited FDA jurisdiction to products marketed with ‘therapeutic’ structure/function claims have described such claims as those that imply drug-like effects.18 And consumer tDCS manufacturers do claim that their products have such effects—for example, certain FDA-regulated drugs are used for neuro-enhancement purposes similar to those claimed for consumer tDCS products.19 Additionally, as a practical matter, when manufacturers have challenged FDA’s authority to regulate a product, courts more often than not have concluded that FDA has jurisdiction.20

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15 FDA’s draft guidance on general wellness devices does not help to answer whether tDCS products are devices because it takes no position on whether particular wellness statements are structure/function or disease claims. Instead, it announces a proposed policy of declining to enforce device requirements for certain low risk products. FDA, Draft Guidance, General Wellness: Policy for Low Risk Devices 2 (2015), http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm429674.pdf. Likewise, although FDA apparently declined to require that one manufacturer obtain authorization to market its consumer tDCS product, without knowing the basis for that decision, it is not particularly useful for assessing which tDCS products are devices. See Thync, Thync Launches First Wearable to Shift Your State of Mind June 2, 2015, http://www.thync.com/resources/press-release/thync-launches-first-wearable-to-shift-your-state-of-mind.


18 One could question whether a meaningful judicially created therapeutic limitation exists outside the tobacco context. For example, in ‘Sudden Change’, the Second Circuit analyzed whether a cream was a cosmetic intended to alter appearance or a drug intended to affect the body’s structure or function. 21 U.S.C. § 321(g), (i) (2015). The court explained that structure/function claims were those that represent ‘that the product will affect the structure of the body in some medical- or drug-type fashion, in some way other than merely “altering the appearance”’. The court concluded that the cream was a drug but noted that if the manufacturer avoids . . . claiming to affect the structure of the skin in some physiological . . . way, then, assuming arguido that no actual physical effect exists, the product will not be deemed a drug’. ‘Sudden Change’, 409 F.2d at 742. It, therefore, appears that the court required only a pure structure/function claim to reach its conclusion, and the court might have considered the cream a drug solely on the ground that it actually affects the skin’s structure.


20 See eg Adam Candeub, Digital Medicine, the FDA, and the First Amendment, 49 GA. L. REV. 933, 954 (2015).
In sum, it seems unlikely that a court would decide that FDA cannot regulate a product that is designed to deliver electrical current to the brain, is marketed with claims that FDA has long identified as structure/function or disease claims in other contexts, and is intended to support or enhance cognitive and other functions like some drugs are thought to do. Thus, to the extent Wexler relies on FDA jurisdiction to argue that a comprehensive regulatory scheme exists for consumer tDCS products, her claim may be stronger than she acknowledges.

Of course that FDA can generally regulate consumer tDCS products (in my view) does not mean that it will. FDA can, and does, exercise its discretion not to enforce requirements in certain circumstances. But FDA recently held a public workshop on regulating neuro-enhancement devices such as tDCS products, which indicates that the agency is seriously considering regulating these products (and likely believes that it could regulate at least some products).

If FDA decides to regulate consumer tDCS products, it will face challenging questions about how it should regulate them. The core of FDA’s public health mission is to assure that marketed devices are safe and effective, which generally means that a device’s benefits outweigh its risks. FDA has extensive experience assessing risks and benefits in the context of treating disease. But what do safety and effectiveness mean for products intended to improve cognitive function in healthy individuals, rather than treat deficits? This question is one with which FDA may not have much experience because many neuro-enhancement products are either supplements not subject to pre-market review, or drugs approved for disease treatment but used off-label for enhancement.

It is also a question that could reasonably be answered in different ways. For example, we might think that the enhancement is an inherently less valuable, and more subjective, benefit than treatment, and therefore the risks of enhancement products must be quite low to be outweighed by their benefits. On the other hand, we might think that individuals who are sick deserve special protection from unproven or risky products and, therefore, less favorable or less certain risk-benefit profiles are acceptable for enhancement products that consumers voluntarily decide to use.

A related question is how much regulation is needed to reasonably assure the safety and effectiveness of tDCS products (however defined). This question arises partly because FDA generally categorizes devices into Class I, II, or III, with Class I devices subject to the least stringent regulatory controls and Class III subject to the strictest requirements. Beyond classification, FDA might use enforcement discretion to tailor further which requirements apply to which tDCS products, as it has done for certain other novel technologies. This option gives the agency significant flexibility to devise a scheme appropriate for regulating tDCS products (and, perhaps, for allocating FDA’s limited resources). This flexibility may also help forestall complaints about FDA

21 For example, it may (or may not) be the case that FDA decided to exercise its discretion not to enforce pre-market review requirements for Thync’s product. See Thync, supra note 15.
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regulation being burdensome or stifling innovation. But it currently might be difficult to determine the optimal level of regulation because of uncertainty about consumer tDCS products’ benefits and risks. 25

Finally, part of FDA’s mission is also to assure that the public has accurate, balanced, and non-misleading information about devices. Accordingly, FDA will need to determine what kinds of claims manufacturers should be permitted to make, to help ensure that consumers understand the risks and benefits of cognitive wellness or enhancement devices. Courts’ recent inclination to find more expansive First Amendment protections for commercial speech may complicate FDA decision-making, particularly because, as with drugs used for neuro-enhancement, FDA might authorize a tDCS product for disease treatment that is then used (and potentially marketed) off-label for neuro-enhancement. 26

I do not aim to answer these questions here, nor do I intend to suggest that this list identifies all questions associated with neuro-enhancement devices. Indeed, FDA raised additional questions at its public workshop, and numerous others have raised social and ethical questions that are outside FDA’s purview, such as whether individuals should engage in neuro-enhancement and how to ensure fair access to neuro-enhancement. Although Wexler provides an excellent start to a serious discussion about regulating consumer tDCS products, these questions show that challenging issues will continue to arise as FDA, and others, consider whether and how to regulate neuro-enhancement devices.

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25 See eg Farah, supra note 19, at 380.