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The Brain, Cognitive Enhancement Devices, and European Regulation

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Abstract
From the Introduction:

Exciting advances in neuroscience have given rise to devices—now being sold worldwide—which hold the promise of enhancing human cognition. This concerns Maslen et al.—authors of the article, *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*—because there are unaddressed possible harms from such equipment. Cognitive enhancement devices (CEDs) are currently entering the European market without special regulations. Their unique ability to influence the brain in potentially deleterious ways is not being accounted for by the law, exposing consumers to risk.

In arguing for such regulation, Maslen et al. present risk analyses of certain devices that interact with the brain. They then propose CED-specific additions to existing European medical device regulation. First, they recommend a positive list of CEDs to be regulated. Second, they offer a three-tiered framework for categorizing CEDs, determining market approval, and what level of government scrutiny they receive based on risks and benefits.

The authors' assessment, while demonstrating legitimate concerns, presents a flawed analysis of CEDs and is ultimately unnecessary. We disagree with their definition of CEDs and classifications for certain devices. Moreover, we believe that the regulatory gap Maslen et al. seek to address is not as profound as they portray. Steps are underway to fill this gap in the immediate future, obviating the need for their proposal. Finally, we argue that the authors incorrectly balance risk and benefit when determining CED market approval.

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The brain, cognitive enhancement devices, and European regulation

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INTRODUCTION

Exciting advances in neuroscience have given rise to devices—now being sold worldwide—which hold the promise of enhancing human cognition. This concerns Maslen et al. —authors of the article, *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*—because there are unaddressed possible harms from such equipment. Cognitive enhancement devices (CEDs) are currently entering the European market without special regulations. Their unique ability to influence the brain in potentially deleterious ways is not being accounted for by the law, exposing consumers to risk.

In arguing for such regulation, Maslen et al. present risk analyses of certain devices that interact with the brain. They then propose CED-specific additions to existing European medical device regulation. First, they recommend a positive list of CEDs to be regulated. Second, they offer a three-tiered framework for categorizing CEDs,

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REVISITING THE DANGERS OF CEDs

Maslen et al. attempt to show the need for stricter regulation of CEDs in Europe by presenting potential adverse effects of two devices—neurofeedback equipment (NE) and transcranial direct current stimulation (tDCS)—and entertaining the possibility that more severe risks will be discovered. But based on current evidence, their argument is unconvincing. Contemporary scholarship shows no serious harm associated with the use of NE or tDCS. Furthermore, we contend that NE should not even be considered a CED, thus removing it from this discussion. Still, the authors raise noteworthy points regarding the possible future harms of tDCS. Because tDCS directly influences neural functions, such as interconnectivity and plasticity, concern over undiscovered harms is warranted and favors increased caution.

Neurofeedback is described by Maslen et al. as 'a type of biofeedback that uses real-time displays of brain activity based on neuroimaging, often with the goal of enabling the person to regulate his or her brainwave activity.'[1] Per the authors' own description, NE is not a CED at all, but rather a self-monitoring tool. It presents information regarding an individual's brain activity but does not influence brain function, let alone enhance it. What actually affects the brain is therapy used with NE whereby subjects attempt to manipulate their brainwaves behaviorally. NE is, in essence, analogous to a heart-rate monitor since both devices provide data regarding the target organ but do not directly influence it. A heart-rate monitor can also be used with therapy to influence the heart, but it is not considered a 'cardiac enhancement device.' In addition, the adverse effects Maslen et al. ascribe to NE—'headaches, muscle twitches, tics, mental fogginess, and sleep disturbance'[2]—are actually associated with concurrently administered behavioral therapies, not the equipment.[3]

NE could theoretically be a CED, if one adopts the article's broad definition: '[A] piece of equipment or combination of pieces of equipment that is sold and used to affect the functioning of the brain such that it performs better in at least one cognitive domain.'[4] Yet this definition would then inappropriately include other implements commonly used to enhance aspects of cognition, such as software, videos, and books, detracting from the clarity of the discussion of CED regulation. Including these objects

1 Hannah Maslen et al., *The Regulation of Cognitive Enhancement Devices: Extending the Medical Model*, 1 J. L. Biosciences 68, 73 (2014) [*hereinafter* Maslen et al.].

2 *Id.*

3 D. Corydon Hammond & Lynda Kirk, *First Do No Harm: Adverse Effects and the Need for Practice Standards in Neurofeedback*, 12 J. Neurotherapy 79 (2008).

4 Maslen et al., *supra* note 1, at 70.

is unreasonable and impractical—which the authors acknowledge[5]—just as it is to include NE. Perhaps the authors have concerns regarding the therapy used with NE, but these are outside this article's scope.

Direct current stimulation of the brain, however, is entirely different. This is generally performed through tDCS, a 'non-invasive technique in which a device sends a small direct current between electrodes placed on the scalp to stimulate or inhibit spontaneous neuronal activity.'[6] Rather than monitoring self-generated brain activity, tDCS artificially introduces electricity into the brain to directly influence function. It is therefore appropriately considered a CED.

Maslen et al. raise numerous concerns regarding the risks and potential harms of tDCS. They note that (1) misplaced electrodes can fail to produce desired effects, or produce undesired ones; (2) electricity may be applied at incorrect intensities and cause damage; (3) it may negatively interact with psychoactive substances and drugs; (4) it may produce unintended and sustained effects even when used correctly; and (5) it may pose greater risk to children.[7] The first three risks appear readily addressable, and therefore less concerning. Problems with use and strength can be limited with clear instructions and design and manufacturing limits. They can be further mitigated, along with the risk of substance or mental condition interaction, by affixing vivid warnings to these products. Manufacturers are also deterred from marketing devices with these obvious risks, or without clear warnings, since they would quickly prove unprofitable.

The areas where Maslen et al.'s worries seem prescient are the potential unintended consequences of tDCS and enhanced risk to children. These arise from growing understanding of the brain's interconnectedness and plasticity, and brain stimulation's influence on these properties. The brain is the most complex and least understood organ and responsible for all we do and are. It accomplishes its functions through phenomenal interconnectedness, with different regions interacting in complex ways. It is therefore possible that the artificial excitation or inhibition of an area or cognitive ability will inadvertently influence others. Yet this phenomenon, while scientifically grounded,[8] is not inherently troubling. Individuals advance specific cognitive abilities over others when deciding to engage in particular activities. However, while one has the prerogative to improve certain abilities at the expense of others, it is important whether one is making an *informed* choice. Neuroscientists do not yet understand neural functions well enough to accurately predict all of the unintended consequences of artificial stimulation to given brain regions. While current research does not show serious harm from brain stimulation, the lack of additional understanding supports stricter regulation of CEDs than products in general.

The potential influence of brain stimulation on neuroplasticity raises additional concerns. Neuroplasticity is defined as 'the brain's ability to change as a result of experience' by altering 'the patterns of synaptic connectivity between neurons.'[9]

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5 *Id*. at 74.

6 *Id*. at 70.

7 *Id*. at 71.

8 See *e.g.* Teresa Iuculano & Roi C. Kadosh, *The Mental Cost of Cognitive Enhancement*, 33 J. Neurosci. 4482, 4486 (2013) ('[C]urrent results clearly demonstrate that enhancement of a specific cognitive ability can happen at the expense of another ability').

9 Jamie Ward, The Student's Guide to Cognitive Neuroscience 181 (2nd ed. 2010).

Synapses and neural circuits strengthen or weaken based on activity. Repeated activation reinforces neural patterns; disuse attenuates them. TDCS potentially influences this by allowing humans to modulate which pathways are excited or inhibited, when, for how long, and to what degree. However, while individuals who employ tDCS for enhancement hope for cognitive improvement, it could result in long-term unintended negative effects. This risk may be heightened in children, whose brains are still developing; in this population, relatively modest changes in neural function could have considerable downstream effects.[10]

Despite these concerns, discussion of possible negative effects of tDCS is, presently, almost entirely speculative. Current scholarship shows no serious side effects. The scientific community, however, is also not incentivized to investigate possible risks. The goals of tDCS research are predominantly to explore the neural basis of behavior, demonstrate patient therapeutic benefits, or, in a minority of studies, enhance healthy individuals. Discovery of possible negative impacts has been largely tangential to these investigations, as there is little money or prestige in showing that tDCS could be harmful. This situation coupled with the brain's complexity, interconnectedness, and plasticity favors approaching CEDs with enhanced caution, and we agree with Maslen et al. in this regard.

EUROPEAN REGULATION OF CEDs

The known and potential harms of CEDs lay the groundwork for Maslen et al.'s main proposal: the creation of a framework for CED-specific European regulation. In this effort, however, the authors present a model that appears both unnecessary and at least partially ill-conceived.

The Lack of Sufficient Regulation

Maslen et al. contend that there is currently no European regulation governing CEDs beyond general product safety guidelines.[11] This is true, but not for the reasons they articulate. The authors argue that CEDs do not fall under the ambit of European regulation of medical devices[12]—the only realistic category for regulatory placement—because (1) placing them under the current definition for 'medical device' makes that definition overly broad and (2) this regulation requires a device to have a 'medical purpose,' which CEDs do not possess under the phrase's present legal interpretation.[13] We find these arguments problematic.

First, including CEDs under the current definition for a medical device does not result in the authors' problem of overbroadness. The relevant portion of the Medical Devices Directive (MDD) defines a medical device as:

> [a]ny instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper

[10] See *e.g.*, *Id.* at 369 (Explaining that the human brain takes a significant amount of time to structurally mature and how the process can continue for as long as 20 years).

[11] Council Directive 2001/95/EC, art. 2, § (b).

[12] Council Directive 93/42/EEC, art. 1 § 2(a).

[13] Maslen et al., *supra* note 1, at 74 and 75.

> application, intended by the manufacturer to be used for human beings for the purpose of:…investigation, replacement or modification of the anatomy or of a physiological process.[14]

The authors believe that by allowing this to encompass CEDs, 'the definition would then problematically extend to anything that alters the brain: books, DVDs and computer games.'[15] Yet it seems farfetched. These items are so starkly different from anything that could fall under this framework that there is no realistic possibility of their inclusion. Furthermore, the items listed are not intended to investigate, replace, or modify anatomy or a physiological process. The changes in behavior and brain function created by a book or DVD are mediated by the normal neurophysiological processes of the brain, rather than supraphysiological external manipulation, as with CEDs like tDCS. One might argue that since software is included in the MDD definition, and software also acts indirectly on individuals, the authors' breadth concerns are valid. But the software must be 'necessary for [a device's] proper application.' No book, DVD, or computer game fulfills this requirement. The authors' overbroadness issue is therefore illusory.

Second, Maslen et al. fail to cite the actual law when claiming that CEDs do not fulfill the MDD's medical purpose requirement. This requirement is interpreted from the language above requiring a device be 'intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes'—i.e. medical purposes. Although affixed to the software inclusion portion of the definition, this phrase applies to all medical devices.

The authors cite a generally accepted interpretation of the language by the European Commission (EC) to exclude devices not intended by their manufacturers for a medical purpose.[16] Yet the actual legal weight of this phrase emanates from a 2012 opinion from the Court of Justice of the European Union. It makes clear that the definition of a medical device 'covers an object conceived by its manufacturer to be used for human beings for the purpose of investigation of physiological process only if it is intended for a medical purpose.'[17] Manufacturers are given considerable latitude to determine applicable regulations to their products. This does not mean, as the authors state, CEDs 'are not identified by the definition as devices for regulation.'[18] Rather, they are unlikely to fall under the MDD because manufacturers targeting the general market are discouraged from intending them 'for a medical purpose', because this mandates costlier and more time-consuming requirements.

We must note that the practical fact that CEDs are not under the MDD will soon be moot. An EC proposal for amendment of the MDD that is likely to come into effect

[14] Council Directive, *supra* note 12, art. 1§ 2 (a).
[15] Maslen et al., *supra* note 1, at 74.
[16] *Id*. at 75.
[17] Case C-219/11, Brain Products GmbH v. BioSemi VOF, 2012 EUR-Lex CELEX LEXIS 62011CJ0219 (Nov. 22, 2012), http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402800429191&uri=CELEX:62011CJ0219 (accessed 11 August 2014).
[18] Maslen et al., *supra* note 1, at 75.

in the next few years[19] will specifically define a medical purpose and thus remove this decision from manufacturers. The relevant portion will likely read:

> '[M]edical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:…investigation, replacement or modification of the anatomy or of a physiological process or state.[20]

Manufacturers will no longer determine whether a CED is intended for a medical purpose because this legal phrase will be clearly defined. CEDs like tDCS—and devices like NE—will be encompassed under the new language as medical devices intended for investigatory or modifying medical purposes. Since the authors feel that MDD regulation of CEDs is not appropriate regardless, this forthcoming change does not negate their argument. It does, however, show that the hole they perceive in European law will soon be filled and a regulatory gap will not be an incentive for their proposals.

Finally, there is one more caveat to the claim that Europe currently lacks CED-applicable regulation beyond general product safety guidelines. While overarching *European* regulation does not exist, this may not be the case for individual states. The European directive concerning general product safety even encourages enhanced state regulations for items with higher risks than general products.[21] The authors' argument would have been bolstered by showing that the ways individual states handle CEDs and the autonomy allowed them are somehow deficient.

The Way Forward

To address the lack of adequate European CED regulation, Maslen et al. advocate significant MDD alteration. They contend that it should include a 'positive list' of 'cognition improving or facilitating devices' and a three-tiered legal framework for categorizing CEDs, determining market approval, and the level of government scrutiny they receive based on risks and benefits.[22] These devices would not be defined as medical devices, but classified and regulated under the Directive through additional CED-specific provisions. The authors feel these additions necessary because they fear that (1) including CEDs under the MDD definition for medical devices makes it overbroad to the point of including too many items, and (2) CEDs require unique considerations and risk/benefit balancing that the MDD cannot apply as is. We disagree on both fronts.

First, the definitional problem Maslen et al. present, as noted above, is both illusory and mitigated by the impending modification of the MDD. This change will eliminate the ambiguity of the medical purpose requirement and clearly place CEDs

[19] See *e.g.* United Kingdom Medicines and Healthcare Products Regulatory Agency, *New Legislation on Medical Devices*, http://www.mhra.gov.uk/Howweregulate/Devices/Legislation/NewLegislationonMedicalDevices/ (accessed 11 August 2014) (Providing a timeline for when proposed European modifications to the MDD will come into effect).

[20] European Commission Proposal 2012/0266 (COD), art. 2, § (1).

[21] Council Directive, *supra* note 11, at art. 3 § 2, 3; art. 5 § 1, 3; art. 8 § 1; art. 9 § 1.

[22] Maslen et al., *supra* note 1, at 92 and 93.

under its ambit. Once introduced, CEDs will fall under the category of Class I medical devices.[23]

Second, CED-specific language is unnecessary because the MDD is already equipped to individually analyze any device subject to its authority.[24] Because the unique attributes, risks, and benefits of CEDs will be considered once the MDD is revised, CED-specific requirements are superfluous.

Balancing device risks and benefits is highly dependent on context. When treating ill patients, the importance of curing or alleviating health maladies generally allows for tolerance of greater risk. Simultaneously, illness can compromise patients' autonomy in ways that necessitate increased certainty of benefit. Conversely, in consumer contexts, users generally act with significant autonomy, are free to self-assess benefits, and are not contending with health ailments. As such, the threshold for unacceptable risk should be low, as should that for demonstrable benefit.

The MDD is flexible and capable of risk/benefit balancing in both situations. CEDs will soon be Class I medical devices subject to the Essential Requirements[25] and class-specific EC Declaration of Conformity[26] provisions of the MDD. These allow an ad hoc balancing to ensure 'that any risks which may be associated with [a medical device's] intended use constitute acceptable risks when weighed against the benefits.'[27] Officials can therefore account for the patient or consumer context.

We do, however, feel that a rough framework is helpful in balancing the specific risks and benefits of medical devices intended for consumers. But we contend that this framework should be presented as an EC recommendation for the application of the MDD to these devices rather than a new MDD provision. Our recommendation would suggest that, in general market settings, only risk should be noted for medical device approval and consumers should determine benefit. Consumers would be well informed as to risks and benefits discovered through mandatory clinical trials due to the MDD's information and labeling requirements,[28] but benefits would not be a factor in allowing products to market because these are best assessed by individual purchasers.

In this regard, we disagree with Maslen et al.'s method of assessment. The authors suggest that both risk *and* benefit be considered when defining categories of regulatory oversight for CEDs. They also contend that devices with low risk need not prove benefit and be exempt from further regulation.[29] These are flawed assertions because, first, the term 'benefit' is nebulous and highly subjective in consumer settings. The authors claim that they can assess benefit through measurement of 'wellbeing.'[30] However, we argue that consumers are the best assessors of what is beneficial to them. It seems overly paternalistic for states to dictate to individuals the benefit of a product on the general market, and then use this unilateral judgment to determine acceptable risk associated

[23] Council Directive, *supra* note 12, at annex IX, § III.1.1.

[24] See *e.g. Id.* at annex I (Providing a general framework enabling officials to weigh the risks and benefits of a given medical device individually).

[25] *Id.*

[26] *Id.* at annex VII.

[27] *Id.* at annex I, § I.1. See also, *Id.* at annex I, § I.6 ('Any undesirable side-effect must constitute an acceptable risk when weighed against the performance intended.').

[28] *Id.* at annex I, § II.13.

[29] Maslen et al., *supra* note 1, at 92 and 93.

[30] *Id.* at 87.

with it. Furthermore, we disagree with the approach to low-risk devices. They should not be excused from regulation because the law is concerned not only with initial assessment, but also with continued safety. Excluding low-risk CEDs from ongoing oversight seems especially dubious, since so much concerning the brain, what affects it, and how remains unknown.

CONCLUSION

As we look toward a future where people increasingly use technology to manipulate their cognitive abilities, the need for well-defined regulations that balance safety with the autonomy of consumers and manufacturers is clear. Luckily, to this effect, Europe already has an excellent foundation. Therefore, while evincing deep knowledge and concern for the safety of CEDs and consumers, Maslen et al.'s propositions appear flawed and ultimately unnecessary. Europe's current trajectory for CED regulation is quite positive, and will likely only require a limited amount of adjustment to produce an exceptionally well-constructed regulatory framework.