



Outstanding questions concerning the regulation of cognitive enhancement devices[†]

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ABSTRACT

The authors (Maslen et al., 2014) propose to regulate cognitive enhancement devices (CEDs) as medical devices. Extending medical device regulations to CEDs raises some important questions that need to be adequately addressed before it makes sense to pursue this path. A first problem concerns the definition of ‘cognitive enhancement’ and ‘CEDs’. Where does treatment end and enhancement begin? Secondly, since most CEDs such as neurofeedback and transcranial direct current stimulation are currently performed by non-medical health care providers, how will this regulation impact the current practice, and which requirements need to be put in place to regulate their use? Thirdly, distributive justice issues present an obvious ethical limitation. Fourthly, if CEDs are indeed prescribed off-label similar to the off-label prescription of psychopharmacological enhancers by MDs, this will pose problems regarding a lack of sufficient knowledge and expertise due to the highly specialized nature of CEDs. And finally, are we faced with unnecessary worries and unrealistic hopes when it comes to CEDs? In sum, we propose to regulate them regarding product safety and restrict them to competent adult use including professional oversight where indicated.

KEYWORDS: cognitive enhancement, tDCS, neurofeedback

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While intuitively it is evident that tools such as cognitive enhancement devices (CEDs) that can pose a health risk to the consumer should be regulated, the question is how? This is addressed in the manuscript by Maslen and co-workers. The authors propose to extend the medical device legislation to cover CEDs by focusing on devices such as transcranial direct current stimulation (tDCS) and neurofeedback.

There are basically four options for regulation of CEDs.

1. Keep a status quo, ie don't regulate.
2. Regulate CEDs as medical devices, as proposed by the authors.
3. Regulate them only on product safety, in a way similar to food supplements or preventive tools like toothpaste.
4. Regulate them on product safety, and additionally regulate the personal use of CEDs, in a way similar to the use of alcohol.

A first question is whether these devices do need regulation? Are they really posing a health risk that warrants such a regulation? Techniques such as neurofeedback, transcranial magnetic stimulation (TMS), or tDCS are typically framed as *non-invasive* brain stimulation techniques.¹ Or would a regulation like alcohol, ie not below a certain age limit, be sufficient, for example with warning signs on the devices that they might pose a threat, as in cigarettes and alcoholic drinks? Whereas the authors propose the second of the four options, we argue that there are some issues that need to be addressed before this can be universally adopted. While these are being addressed, we propose to use the fourth option, ie to regulate these devices on product safety in combination with regulating their personal use, but without classifying them as medical devices.

To start with, there is a problem with the definition of cognitive enhancement, and if cognitive enhancement per se is hard to define, how do you define a CED? We need to ask ourselves whether we are prepared to change the definition of health used by the Medical Devices Directive (MDD), currently demanding diagnostic and/or therapeutic medical purposes, in such a way that it includes enhancement purposes. It is common knowledge that one cannot easily draw a line between treatment and enhancement.² Whether or not we consider an intervention as enhancement rather than treatment depends on our definition of health and disease. At what point does an intervention go beyond the restoration and sustainment of good health and become an enhancement (ie pursues a non-medical purpose)? If we define good health as widely as the World Health Organization does, involving complete physical, mental, and social well-being, then there seems to be no essential difference between plastic surgery for medical reconstructive versus esthetic reasons. Both can lead to an improvement in an individual's physical, mental, and social well-being. Similarly, how we differentiate between normal and pathological functioning is a normative issue that draws upon our definition of health and disease.

The same problems arise when we aim to provide a comprehensive list of CEDs. How do you define a CED? The authors define a CED as 'a piece of equipment or combination of pieces of equipment that is sold and used to affect the functioning of

¹ Anna-Katharine Brem et al., *Is Neuroenhancement by Noninvasive Brain Stimulation a Net Zero-Sum Proposition?* 85 NEUROIMAGE 1058, 1068 (2014).

² Maartje Schermer, *Health, Happiness and Human Enhancement—Dealing with Unexpected Effects of Deep Brain Stimulation*, 6 NEUROETHICS 435, 445 (2013).

the brain such that it performs better in at least one cognitive domain (eg memory, attention, learning, facial recognition)'. Are there benefits in separating devices with a medical purpose from those without such a purpose, as suggested by the European Commission? How do you determine which devices fall within the realm of devices intended for cognitive enhancement? Or, do we want to change the definition of medical devices to include enhancement purposes?

Moreover, cognitive enhancement in the setting of a treatment for cognitive decline is different from cognitive enhancement in a healthy person, who wants only to enhance his/her normal skills, analogous to medication being taken for a disease, eg methylphenidate taken for attention deficit hyperactivity disorder versus for enhancement in sports. Furthermore, what about prevention of cognitive decline? Prevention of cognitive decline from a neurobiological point of view can be regarded analogous to toothpaste in the prevention of tooth decay. It is clear that in a tooth abscess, antibiotics and possibly surgery are needed, which are medically regulated, whereas toothpaste is not. Does that mean that when a company only promotes its CED as a preventive device, it will fall under different regulation? The authors have foreseen this and propose to make up a list of devices that can be used both for preventive and enhancement purposes, analogous to a list of specially regulated medications in many countries.

This approach could suggest that the same rules be applied as in the medication world. However, the difference between a medication and a food supplement is not always clear. For example, in some countries melatonin is freely available, not restricted by medical regulation, whereas in other countries it is considered a medication. Medication is used as a therapy whereas food supplements are used for enhancement, or prevention of diseases. But some medications are used off-label as cognitive enhancers, eg modafinil or amphetamines, and some food supplements are used as treatments, or are perceived as such, eg melatonin. Neurofeedback, TMS, or tDCS could be similarly prescribed off-label for enhancement purposes and similar differences between countries could arise which then pose potential problems involving cross border use.

Another important aspect of regulating tDCS and neurofeedback as medical devices is the consequences of applying medical device regulation to tDCS, TMS, and especially neurofeedback. Most neurofeedback now is performed by non-medical health care providers. Does the regulation of the CED then require new regulations for who can apply them? Will only MDs be permitted to use CEDs, or nurses or psychologists under supervision of an MD? And will consumers need a prescription for a CED and subsequently get a device at a pharmacy-like place? Will this involve a minimum number of training hours with subsequent accreditation under the supervision of an MD, nurse, psychologist, or other trained expert?

Schermer argues that although some enhancements may fall within the goals of medicine, we have good reasons to limit the kind of interventions MDs are allowed or required to do.³ It is obvious that the use of CEDs does not belong to the core goals of medicine, and it is questionable whether it should. However, one might argue that the use of CEDs should be seen as an extended goal of medicine. Or one might argue that the goals of medicine need to be adapted in response to new technological challenges such as the use of tDCS for enhancement purposes. While enhancement should not be

³ *Id.*

seen as a part of an MD's medical duty, it's clearly less problematic if MDs with the required expertise do view improvements beyond curing and preventing disease as one of the goals of their profession. It is unclear, however, why the use of CEDs should be limited to the medical domain and by extension, and why its regulation should fall under the medical devices legislation. As medical skills and expertise are scarce resources, we should not take this issue lightheartedly. Do we want to allow or promote the use of valuable medical skills and expertise for enhancement purposes rather than reserving these scarce resources more narrowly for curing and preventing disease?

Although the authors mention distributive justice as an ethical limitation when enhancement interventions are brought within the publicly funded medical domain, they seem to question the argument's strength based upon the fact that similar issues may arise, and do arise, when considering treatment. However, their consistent counter-argument only holds when one does not draw a morally relevant distinction between treatment and enhancement (eg defends the position that both treatment and enhancement are mere improvements of human functioning). Individuals that do draw a morally relevant distinction between treatment and enhancement may argue that there are good reasons to preferentially allocate resources to curing, alleviating, and preventing disease rather than to enhancing healthy individuals. Hence, the argument's validity crucially depends on one's normative position.

Forlini and Racine mention the scarcity of health care resources as one of their three main reasons to dismiss the ethical acceptability of off-label prescription of cognitive enhancers.⁴ They also state that 'with uncertain benefits and clear harms, it is difficult to support the notion that physicians should prescribe a medication to a healthy individual for enhancement purposes'. Although good reasons could be given to support such a claim, categorically banning off-label prescription by physicians will likely drive the use of cognitive enhancers underground and should therefore not be the preferred strategy.⁵ However, if we allow off-label prescription either by medical or non-medical professionals, several challenges will need to be addressed.

With regard to the off-label prescription of psychopharmacological cognitive enhancers, a survey among primary care physicians in Germany found that while a relatively high proportion of physicians have been asked to prescribe cognitive enhancers, only a minority is well informed about the possibilities of cognitive enhancement.⁶

Due to the specialized nature of CEDs, a lack of sufficient knowledge and expertise might be even more problematic in this domain. Hence, specialized non-medical health care providers or other skilled experts may be better suited to safeguard the correct use of CEDs and to assess whether continued use is warranted. Potentially much more problematic however is personal use of such devices without any professional or clinical guidance/oversight. If we want to avoid adverse reactions or ineffective use of CEDs, tDCS and neurofeedback training need to be tailored to the individual due to non-uniform effects among individuals. As already alluded to by the authors, these

⁴ Cynthia Forlini & Eric Racine, *Stakeholder Perspectives and Reactions to "Academic" Cognitive Enhancement: Unsuspected Meaning of Ambivalence and Analogies*, 21 PUB. UNDERSTANDING SCI. 606, 625 (2012).

⁵ Dan Larriviere et al., *Responding to Requests from Adult Patients for Neuroenhancements: Guidance of the Ethics, Law and Humanities Committee*, 73 NEUROLOGY 1406, 1412 (2009).

⁶ Elisabeth Hildt, Klaus Lieb & Andreas G. Franke, *Life Context of Pharmacological Academic Performance Enhancement Among University Students—A Qualitative Approach*, 15 BMC MED. ETHICS 23 (2014).

non-uniform effects can be traced back to the heterogeneity of cortical excitability and brainwave activity in (potential) users. Some medications can change excitability of the brain, making the brain more or less responsive to tDCS. But some medication can enhance the effect of tDCS by a factor of 20, and it is unknown what some food supplements do on tDCS. Thus, what is safe for one person is not safe for another person. This is analogous to drinking alcohol when one takes medication and comes to the core question of the discussion. Should these CEDs be considered like alcohol, which can have cognitive enhancing effects at a low dose but worsening at higher doses and be regulated rather like alcohol than as a medical device? Potentially, as is the case for driving a car or in some countries for the possession and recreational use of a fire weapon, requiring some kind of training and certificate to legally allow the personal use of moderate- to high-risk CEDs?

As mentioned, the critical question remains whether these devices really pose such a health risk that requires *medical device* regulation? And secondly, whether they really amount to enhancing effects, and are not just statistical findings rather than behaviorally relevant cognitive improvements? The popular press, internet sites, and social networks are widely advocating the use of TMS and tDCS as CEDs.⁷ In stark contrast, similar to medications for enhancement purposes (eg Selective Serotonin Reuptake Inhibitors and stimulants as cognitive enhancers), there is currently no substantive evidence that so-called CEDs produce lasting enhancement effects outside of research or clinical settings, ie real-world enhancement effects.⁸ In a certain way both are linked. If these CEDs do not exert a real improvement in cognitive abilities, ie if they are perceived as ineffective, nobody will continue using them, and thus the risk for society is very limited. Or, if they are perceived as effective by the general public, but in reality do not amount to any real enhancement effects, shouldn't we focus on education and public awareness rather than *medically* regulating devices that offer no real benefit? In fact, medically regulating these devices, especially at present, may create and strengthen the illusion that these devices are indeed beneficial. On the other hand, if they really have an important beneficial effect, should we medically regulate their use, and thereby potentially lose the prospect of great societal benefit?

Rather than urging for the regulation of CEDs as medical devices, shouldn't we urge for the regulation of the *use* of CEDs, especially those CEDs that have corollaries in the medical domain and are currently on the market? This could potentially be done within the MDD by overseeing the use of CEDs based upon an ancillary list, or alternatively via a combination of product safety regulation and specific legislation concerning the use of CEDs (eg similar to minimum drinking level laws for alcohol use and driving license laws). A possible intermediate solution would be to start with the fourth option listed above, and if CEDs really prove to be efficacious as enhancers, to regulate these devices as medical devices. By being safe, we suggest first of all that the amount of current delivered by the device is stable without peak current deliveries, and that what is set as output is exactly the delivered current output. Safety limitations can be built into the devices, so that they stop automatically after a certain amount of charge is delivered to the brain,

⁷ Brem, *supra* note 1, at 1059.

⁸ Nuffield Council on Bioethics, *Novel neurotechnologies: intervening in the brain*. http://nuffieldbioethics.org/wp-content/uploads/2013/06/Novel_neurotechnologies_report_PDF_web_0.pdf (last accessed September 10, 2014).

preventing overdoses. Limitations on the maximal amplitude and maximal duration for that amplitude can be programmed to remain within safety limits. Furthermore, a manual should be supplied showing the safe application of the device, eg the locations where electrodes can be applied safely, reminding the users to apply enough water to keep the electrodes wet, etc. In view of potential risks, albeit very rare, it's advisable to limit the use of CEDs to competent adults, analogous to other mind-influencing techniques, such as the consumption of alcohol or soft drugs in some countries or states. Although open for debate and dependent on the type of device, adequate regulation likely requires minimal professional oversight (eg a training session with a trained health care professional) before *personal use* should be allowed. Whereas an adequate level of professional oversight is typically guaranteed in therapeutic settings, this is clearly not the case in non-therapeutic contexts regarding personal use of CEDs.

Moreover, regulation itself is not sufficient. We additionally need to focus on the education of the general public and health care providers concerning the real possibilities, benefits, and risks of CEDs. For example, do medical researchers, doctors, and other professionals have a professional and/or societal duty to correctly inform the public and to prevent misguided beliefs concerning CEDs?

In sum, specific public health guidelines regarding the professional and personal use of CEDs are needed and a number of important questions, of which several are mentioned in this commentary, need to be addressed if the regulation of CEDs as *medical devices* is pursued. In the meantime, we propose to regulate CEDs to be safe and restrict their use to adults including a minimum level of professional oversight.