Medical regulation of cognitive enhancement devices: some concerns

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ABSTRACT

The authors present a cogent and detailed case for altering the Medical Devices Directive to allow regulation of cognitive enhancement devices (CEDs). Protection against significant risk of harm, especially for the vulnerable, and promotion of benefit through informed use of CEDs are all good features of the proposal. However, the pre-market approval process has limitations, which we explore. We raise the possibility of ‘risk compensation’ in response to the introduction of safety measures, which could alter its effectiveness. The proposal alludes to use of ‘formally trained practitioners,’ which provide a further tier of regulation for CEDs within the proposal. We consider some positive and negative implications of this aspect of the proposal that might warrant further consideration.

KEYWORDS: cognitive enhancement devices, medicine, regulation, risk, transcranial direct current stimulation

Maslen et al. make a cogent and detailed case for altering the Medical Devices Directive to allow regulation of cognitive enhancement devices (CEDs).¹ We are also in broad agreement with their proposal that this should be done on the basis of well-being rather than medical benefit (as conventionally understood) assessed against risk. We suggest, however, that this has implications that require further thought. Protection against risk of harm, especially for the vulnerable, and promotion of benefit (cashed out as well-being) are all good features of the proposal. However, assessment of

¹ Hannah Maslen et al., The Regulation of Cognitive Enhancement Devices: Extending the Medical Model, 1 J. LAW BIOSCI. 68, 93 (2014).
well-being, harm, and risk, and protection of vulnerable people are all difficult to manage in a pre-market approval process.

One of the primary purposes of the proposal is to reduce the risk of harm that consumers of CEDs may take on in using these devices. The rationale behind this is easy to see: other work by Maslen, and Fitz and Reiner has identified apparently very risky uses of transcranial direct current stimulation (tDCS) devices, mainly by ‘experimenting neuroenhancement consumers’ using do-it-yourself constructions or engaging in self-experimentation with consumer devices. Whether the proposal is likely to be effective in reducing or avoiding those risks is, however, less certain.

An initial cautionary point arises from the concept of risk compensation, a component of the theory of risk homeostasis initially proposed by Wilde. Characterized and developed by Adams using the analogy of a ‘risk thermostat,’ the basic idea is that individuals have a propensity for some level of risk, and when it is known to them that the risk of some activity has been reduced below this level—perhaps by some safety improvement—they will increase the riskiness of their actions until their propensity is met.

The broader theory of risk homeostasis continues to be contested, but there is general agreement that the phenomenon of risk compensation is an important consideration in the development of safety regulation. If those using CEDs, such as tDSC, are comfortable with the level of risk that they are exposing themselves to, pre-market safety standards are unlikely to reduce this risk significantly, or may drive users towards other sources for devices to provide compensatory options.

This is not to say that pre-market safety assessment is without value—either in relation to CEDs or more generally. The value, though, may lie less in risk reduction and more in the promotion of other goods. If consumers are enabled to make more informed choices about CEDs, this may be seen to promote their autonomy. It may also free them up to expend their finite capacity for risk exposure on other pursuits that they may deem valuable or enjoyable. But the risk compensation theory should perhaps make us wary of the assumption that pre-market approval will make users of CEDs safer overall. In the absence of more information on the risk culture in neuroenhancement, and particularly the cohort of experimenting neuroenhancement consumers, we can only mention these as possibilities to consider. A tentative initial conclusion would be that it is doubtful that the proposal will have its greatest safety effects in the latter group, which seems to be the cohort of riskiest users of CEDs.

One reason why the effect of the proposal may be limited in this cohort is that significant risks arise from the way that many CEDs (such as tDCS) are used. The risk of

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these harms occurring would seem not to be diminished by a pre-market approval process only, and the authors concede that this is a limit of the proposal.\footnote{Maslen et al., supra note 1, at 92.} When consumers are determined to use a device in a risky way, regardless of the safety standards it meets prior to market approval, it is very difficult to reduce this risk. But many consumers may have a risk propensity lower than experimenting neuroenhancement consumers, such that the sorts of safety standards proposed may allow them to use safer CEDs, and the production and provision of detailed, evidenced-based information on risks and effects of devices will likely help consumers to use them in a manner that suits their level of comfort with risk.

In order to allow risk–benefit assessment of enhancement devices within medical device regulation based around therapy, Maslen et al. cash out benefit terms of well-being, rather than medical benefit. The proposal makes use of well-being as benefit in two ways. The first is an objective pre-market assessment, informed by expert advice and objective evidence, which centers on the effectiveness of the device in augmenting cognitive capacities that have the propensity to promote well-being.\footnote{Id. at 87.} This resembles what Moore terms ‘thin’ well-being, which he equates with all-purpose goods, primary goods, and basic enabling conditions.\footnote{Andrew Moore, Well-being: A Philosophical Basis for Health Services, 2 HEALTH CARE ANALYSIS 207, 216 (1994).} Agreement may be reached on constituents of thin well-being from within a range of full-blown ‘thick’ conceptions of well-being, and the propensity of CEDs to provide and promote ‘thin’ goods can be assessed more readily on the basis of empirical evidence. This allows Maslen et al. to refer to this as an objective measure of benefit for the purposes of the proposal.\footnote{Maslen et al., supra note 1, at 88.}

The second use of well-being emphasizes that the capacities augmented by CEDs will contribute to the ‘thick’ well-being of individuals variably, based on individual circumstances and psychology. This well-being is referred to as subjective in the sense that it depends upon concordance with an agent’s conception of value and particular circumstances, and ‘thick’ in the sense that comes closer to a full account of what makes a life go well.

The proposal is vague about the thresholds that must be met for devices to be approved for market within ‘moderate-risk profile’ devices, but it is clear that it is the possibility of enhancing well-being in the thick sense that ultimately matters for CEDs. When there is room for reasonable disagreement about the balance of harms and benefits, the device should be approved, allowing promotion of thick well-being by CEDs to be assessed by those the authors judge best placed to do so—individual users. An exception to this is in cases where the purpose of the device is for use in vulnerable groups, such as children and vulnerable adults. Children are to be protected by criminal sanctions for harmful device use by others, and an avenue for safe, beneficial use of CEDs by vulnerable people (both children and adults) suggested by the proposal is the approval of devices for use by ‘formally trained practitioners.’\footnote{Id. at 89.}

Brief reference in the proposal to formally trained practitioners is not developed, and it is not clear what the authors envision. However, use of formally trained practitioners introduces a further tier of regulation that may introduce both benefits and burdens
to the proposal, and the values it seeks to promote. In the concluding sections, we will
discuss this aspect of the proposal and some of its implications.

In keeping with the authors’ stated preference for maximum possible regulatory
colour, the formally trained practitioners are likely to be medical professionals. A fur-
ther reason for this is the emphasis in the proposal that regulation be based on objec-
tive evidence where possible. Use of medically trained practitioners seems more likely
to advance this ideal than for formal practitioners to emerge from complementary and
alternative medicine, which seems another possible avenue for service provision. This
could bring CEDs into medicine in a similar way as aesthetic medicines, such as cos-
metic surgery. On the other hand, it’s not unreasonable to suppose that complementary
and alternative medicine practitioners would have an interest in CEDs; arguing out the
pros and cons of them being able to do so, and what this would mean for assessing risk
to consumers, is a further issue that needs to be considered.

Use of medical practitioners could further the aims of the proposal. A reason stated
by the authors for bringing CEDs into the existing regulation of medical devices is the
substantial similarities that they bear in terms of effects, and in fact the devices may be
identical. One of the values of medical practice is that it helps individuals address health
concerns in ways that promote their well-being. This process can be complicated and
laborious, and although competent individuals are usually best placed to assess what
will contribute to their well-being in the thick sense, they are not infallible, and it can
be advantageous for them to have medical support and skill in furthering this aim. This
seems equally to be the case for use of CEDs such as tDCS, the effects of which depend
so considerably on precise use.12 While formally trained practitioners promote both
the reduction of harm and the provision of benefit for vulnerable groups in particular,
they could also promote this for non-vulnerable people wishing to use the technology
in a more controlled way than they might be able to achieve alone.

Given this, thought needs to be put into what considerations should inform formal
practitioners’ judgements about use of CEDs. Agreement on guidance and policies gov-
erning provision of non-medical benefits in general is something that medicine is still
grappling with, and this is especially the case for those arising from the alteration of
nerve function. The American Academy of Neurology’s Ethics, Law and Humanities
Committee provides an example of one attempt to develop practical guidance to neu-
rologists in responding to adult requests for neuroenhancements.13 It has met with crit-
icism for being too permissive, resting on a favorable evaluation of neuroenhancements
unsupported by sufficient evidence and failing to account for the ‘social factors’ relating
to individual well-being.14 Furthermore, Mendelsohn et al. found disagreement among
neurosurgeons as to assessment of the moral value of use of neural interventions for
benefit in the absence of medical need or psychopathology, even if these were non-
invasive and low risk.15

12 Id. at 71.
13 Dan Larrioviere et al., Responding to Requests from Adult Patients for Neuroenhancements: Guidance of the Ethics,
Law and Humanities Committee, 73 NEUROLOGY 1406, 1412 (2009).
14 Eric Racine & Cynthia Forlini, Responding to Requests from Adult Patients for Neuroenhancements: Guidance of
the Ethics, Law and Humanities Committee, 74 NEUROLOGY 1555, 1556 (2010).
15 Daniel Mendelsohn et al., Neurosurgeons’ Perspectives on Psychosurgery and Neuroenhancement: A Qualitative
Study at One Center, 113 J. NEUROSURG. 1212, 1218 (2010).
However, it is unclear what the normative views of medical practitioners are in much research of this type—in particular, whether a reported negative moral evaluation of neuroenhancement means the practitioners think that it is impermissible to provide or procure such interventions, or they would conscientiously object but refer the consumer to another practitioner, or would, perhaps reluctantly, perform the intervention requested. An anecdote recounted by neurosurgeon Damiaan Denys and reported by Schermer\textsuperscript{16} describes a patient who underwent deep brain stimulation (DBS) for treatment of obsessive compulsive disorder. Her symptoms did not decrease but her reported well-being improved. She asked Denys, ‘could you please leave the settings as they are now, because I finally feel well?’ Denys replied, ‘I am sorry, but my job is to rid you of your complaints, not to make you happy. I’ll put the device off.’

Without further evidence, it would be a mistake to infer that such views are representative of medical practitioners. But assuming that they are at least reasonably widespread, a potential concern arises. While medical professionals may be well placed to advise on the likely effects of CEDs and apply them in precise ways where this will best serve the interests of the consumer, it is far from obvious that they should be permitted to serve as moral gate-keepers, denying access to it on grounds that do not relate to their medical expertise.

On the other hand, compelling medical practitioners to assist with CEDs, when they do not regard such assistance as a legitimate part of their medical role, hardly seems acceptable. Perhaps a compromise solution would involve identifying a sub-population of medical practitioners willing to assume such a role, and willing to advertise that aspect of their range of services in much the way, for example, that some private dentists advertise the various cosmetic procedures that they are willing to carry out.

Even within that willing cohort, however, there may be resistance to certain potential uses of CEDs. What if it was thought possible, for example, to use CEDs to alter sexual preference (so-called ‘conversion therapy’)? A rather bizarre early example of an intervention claiming to successfully achieve this result comes out of the Tulane Electrical Brain Stimulation Program, although this used DBS rather than transcranial stimulation.\textsuperscript{17} Assuming that this had a reasonable prospect of success using the sorts of CEDs the proposal covers, and posed low or acceptable health risks, is it something with which medical professionals would, or should, allow themselves to be involved?

A second possibility may involve the use of CEDs to diminish rather than enhance certain cognitive capacities. While this may at first glance seem an unlikely use of the technology, Earp et al., co-authoring with Savulescu, have argued that it can be prudentially beneficial for individuals to diminish, rather than augment capacities.\textsuperscript{18} One example may involve diminishing episodic memory of traumatic events.

While most of our focus has been on the suggested response to risky CEDs, a further issue may arise with regard to low-risk-profile devices. While such devices may not pose a direct risk to users’ health, we wonder if more attention should be paid to the


\textsuperscript{17} Charles E. Moan & Robert G. Heath, Septal Stimulation for the Initiation of Heterosexual Behavior in a Homosexual Male, 3 J. Behav. Therapy & Experimental Psychiatry 23, 30 (1972).

\textsuperscript{18} Brian D. Earp & Guy Kahane, When is Diminishment a Form of Enhancement? Rethinking the Enhancement Debate in Biomedical Ethics, 8 Front. Sys. Neurosci. 12 (2014).
possibility that such devices may pose indirect risks, specifically by encouraging users to utilize them as alternatives to established medical treatments of proven efficacy. This problem was dramatically illustrated in New Zealand in the context of the ‘quantum booster’ device, which was used in preference to medically indicated chemotherapy. This illustrates that the prospect of less scrupulous complementary and alternative practitioners making pseudo-medical claims about such quasi-medical devices is not entirely far-fetched, and the opportunity costs incurred can be significant. As the authors note, perceived ‘endorsement’ of interventions by the medical profession can increase acceptance of medical interventions in problematic ways. Bringing CEDs under the regulation of the Medical Devices Directive may have this effect, and we have outlined some further potential problems the authors might consider in developing their very constructive proposal.


20 Maslen et al., supra note 1, at 88.