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### VIEWPOINT: PEER-REVIEWED ARTICLE

## Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices?

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### Abstract

Implantable brain-computer interface (BCI) and other devices with potential for both therapeutic purposes and human enhancement are being rapidly developed. The distinction between therapeutic and enhancement uses of these devices is not well defined. While the US Food and Drug Administration (FDA) rightly determines what is safe and effective, this article argues that the FDA should not make subjective, value-laden assessments about risks and benefits when it comes to approval of BCIs for therapy and enhancement. This article also argues that determining BCIs' benefits to society requires deliberations on values that the FDA is neither accustomed to making nor qualified to make. Given the inadequacy of the FDA's safe-and-effective standard to judge devices spanning the spectrum of therapy to enhancement, this article argues that BCI regulation should not be overseen by the FDA.

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### Brain-Computer Interface Devices

A “working brain-to-machine interface”<sup>1</sup> (BCI) designed for both therapeutic and human enhancement<sup>4,2</sup> purposes might be easily dismissed as one billionaire’s pet project, but many similar devices are being developed.<sup>3,4</sup> A facile approach to **brain-computer interface devices**, which we refer to here as *spectrum use devices*, might attempt to fit them into the current US Food and Drug Administration (FDA) safe-and-effective regulatory framework for approving devices.<sup>5</sup> However, we argue that this approach is not sufficient and that, given BCIs’ potential influence on individuals and society, the nature of what is safe and effective and the balance between risk and benefit require special consideration.

BCIs that are currently being developed are claimed to serve therapeutic ends and thus are subject to FDA regulation.<sup>5</sup> However, the **line between therapy and enhancement** for BCIs is difficult to draw precisely. Therapeutic devices function to correct or compensate for some disease state, thereby restoring one to “normality” or the standard species-

typical form.<sup>6,7,8,9,10</sup> However, devices implanted for therapeutic purposes might also enhance individuals beyond the limits of what would be considered normal. A device intended to correct cognitive impairment associated with dementia, for example, may result in above-average cognition.<sup>11</sup> BCIs' blurring of the distinction between therapy and enhancement is further complicated by different perspectives on what is normal and abnormal. For instance, would an IQ below the mean be considered "abnormal" and thus justify implanting a BCI intended to correct a cognitive "deficit"? Almost anyone could then claim therapeutic intent aimed at improving some perceived or real deficiency not only in cognition but also in sensation or motor function. Conversely, for people in the deaf community who do not adhere to the "deficit model" of disability,<sup>6,12</sup> cochlear implants are enhancement rather than therapeutic devices.<sup>6,13</sup> Thus, any BCI will have some therapeutic claim, however thin. At the same time, any BCI could also be **considered an enhancement device**. It is in part this lack of distinction between therapy and enhancement that makes the FDA unqualified to regulate this class of spectrum-use device.

### **Regulating Safety and Effectiveness, Risk, and Benefit**

While BCIs raise multiple ethical concerns, such as how to define personhood, respect for autonomy, and adequacy of informed consent, not all ethical issues justifiably form the basis of government regulation.<sup>6,14</sup> The FDA's standard for evaluating and approving implantable devices is whether a device is safe and effective.<sup>5</sup> As a result, the FDA largely focuses on assessment of engineering technology.<sup>15,16</sup> Four integral features have been identified that help the FDA to regulate approval of implantable devices: materials choices, device design and functionality, risk factors, and implantation procedure.<sup>15</sup> The more similar a proposed device is to an already approved device with respect to these 4 categories, the more likely the device is to receive FDA approval.<sup>15</sup> For BCIs, the approval process entails evaluating the safety of surgical implantation, explantation, and function. Complications such as infections, scarring, probe damage to brain tissue, cerebral edema, and bleeding would be some of the typical outcomes used by the FDA to assess safety.<sup>8,15</sup> In terms of efficacy, therapeutic devices are evaluated in large part based on whether or not they demonstrate consistency between manufacturers' claims and measured outcomes. For BCIs with potential for cognitive enhancement, efficacy can be assessed by the extent of improvement in cognitive function as it is measured by commonly used assessment instruments.<sup>17</sup>

It is well within the FDA's purview to assess devices, including spectrum-use BCIs, strictly along the lines of what is safe and effective. However, implicit in considerations of safety and efficacy is also an assessment of risk and benefit. This assessment involves a value judgment not only about a device's absolute level of risk and benefit but also about what is the right balance between the two. The FDA is not qualified to make these kinds of value judgments about spectrum-use BCIs, however.

Evaluating the benefit of BCIs involves an assessment of the extent to which a device can increase an individual's well-being and chance of living a good life.<sup>17</sup> While the effectiveness of BCIs can be objectively measured, the value placed on that cognitive, sensory, or motor skill improvement will vary significantly among people.<sup>17</sup> A patient with amyotrophic lateral sclerosis who **rejects the stigma of disability** may assign very little benefit to a BCI that improves their motor skills. In contrast, a young computer engineer may place high value on an improvement in cognitive function. Because what is good or beneficial to an individual is subjective and value laden, it is not justifiable for the FDA to base its approval of a device on any one specific notion of what is good or beneficial.<sup>14,18</sup>

Similarly, individual assessment of risk is highly subjective and qualitative.<sup>17</sup> Is there some absolute risk threshold above which a spectrum-use device should not be approved by the FDA? How would that threshold be determined, and would it take into account potential harm both to the individual and to society? Spectrum-use devices also have the potential to introduce risks that are difficult to quantify. For instance, it would be difficult to objectively measure the potential psychological impact of explanting an enhancement device or how individuals would cope with the transition from enhanced to unenhanced states.<sup>19</sup> While these risks are important for the individual and for society to consider, because they are subjective and require value judgments, they are outside the scope of risks that the FDA can evaluate as part of the basis of device approval.

Just as the FDA has no basis for making isolated assessments of a spectrum-use device's risks and benefits, so it lacks a basis for measuring whether the device's benefits outweigh its risks. For strictly therapeutic devices, patients may be willing to "take a gamble" and accept a high level of risk for a therapy that confers minimal or no demonstrable benefit. In addition, patients may wrongly infer that an intervention is beneficial just because it was recommended by a health care practitioner, regardless of its actual measured benefit.<sup>17</sup> Although ensuring that the benefit of a therapeutic device exceeds its risk is part of the FDA's role in protecting vulnerable patients,<sup>14,17</sup> for spectrum-use devices for which assessments of risk and benefit are highly subjective, a more robust consideration for device approval is necessary than is afforded by the narrow categories used by the FDA.

#### **Regulation Based on "Good" to Society**

Finally, there are aspects of the enhancement of individuals that, at the level of society, have potentially very different effects than those of therapy for individuals, particularly aspects related to mental function. While therapeutic interventions upon individuals in the aggregate would not significantly affect society in unexpected ways, enhancement interventions might.<sup>20</sup> BCIs will not simply augment a single person; they present the potential for a bifurcation between "enhanced" and "standard" human beings. As of now, BCIs for human enhancement remain largely untested and their potential unknown, even at the individual level. How do we then judge (let alone legally enforce) the implementation of these devices at the societal level? The potential for social disruption introduced by BCIs for human enhancement would seem to call for government intervention. However, as already noted, judgments about their risks and benefits are not within the realm of competency of the FDA. Rather, it seems that some new governing body would be required to assess risks and benefits of spectrum-use BCIs. In addition to assessing safety and efficacy and risks and benefits, this governing body would need to have some conception of what "good" means for society, which is a difficult prospect in a pluralistic society like the United States.

Some regulations will be vital even if enhancement is allowed, eg, BCIs should be secure against "hacking." Previous presidentially appointed groups on bioethics have indicated this need already exists, but merely repurposing such a group would be too political and lack legitimacy: a new organization needs to be established that has in mind the good of society, not politicians. Needless to say, the establishment of such an organization will require much careful thought.

#### **Conclusion**

With devices like BCIs presenting the possibility of extensive and widespread human change, the current FDA safe-and-effective model of regulation is not robust enough to

do justice to the multifaceted issues posed by these devices. At both the individual and the societal level, BCIs represent a potential for change far surpassing mere therapeutic measures. In place of maintaining standards of health, living, and personhood, BCIs, representing a new wave of biotech, promise deviation from and augmentation of these standards. A new committee or regulatory body with humanistic aims, including the concerns of both individuals and society, ought to be legislated at the federal level in order to assist in regulating the nature, scope, and use of these devices.

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