Regulating the Future:
Navigating Ethical and Legal Pathways in Brain-Computer Interface Technology

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Brain-Computer Interface technology (**BCI**), is on the brink of transforming our lives by providing unprecedented direct communication pathways between the human brain and external devices. A BCI is an advanced technology that facilitates a direct communication pathway between the brain and external devices, effectively bypassing conventional pathways of nerve and muscle action. This technology captures, analyzes, and translates brain signals into commands that can control computer systems or external devices, offering potential restorations or enhancements of human cognitive or sensory-motor functions. The primary goal of BCIs is to assist individuals with disabilities but also to augment human capabilities or provide new ways of interacting with technology.

There are two primary categories of BCIs based on their implementation method. Invasive BCIs involve surgically implanted electrodes inside the brain, offering precise control but with higher risk and complexity. Noninvasive BCIs use sensors placed on the scalp to detect brain signals — safer and easier to use but less precise than invasive methods. Some of the most promising and impactful use cases of BCI technology include these:

- **Neurological Disorder Management and Cognitive Rehabilitation:** BCIs offer groundbreaking methods for managing neurological disorders, such as Parkinson's disease, epilepsy, and stroke rehabilitation. By interpreting neural signals, BCIs can notably help to control prosthetic limbs, wheelchairs, or other assistive devices, thereby improving the quality of life for individuals with mobility impairments.

- **Assistive Communication Devices:** BCIs provide a voice to those unable to speak due to paralysis or such neurological diseases as Amyotrophic Lateral Sclerosis (ALS). By detecting neural signals associated with intended speech or selecting letters from a virtual keyboard, BCIs enable communication through synthesized speech or text.

- **Improving Learning Strategies and Increasing Brain-Based Skills:** BCI, coupled with neurofeedback, could be used to enhance cognitive capabilities such as memory, attention, and problem-solving skills. Through targeted exercises and tasks, students could improve their brain-based skills.

The BCI market has been projected to experience significant growth over the next years. This anticipated growth is fueled by several key factors, including technological advancements in neuroscience and computing, increasing investments in neurotechnology startups, and a growing interest in both medical and enhancement applications of BCI technology. According to a market research study, the demand analysis of the Global Brain-Computer Interface market size and share revenue was valued at around $ 1.8 billion in 2022 and is estimated to grow to about $ 6.1 billion by 2030.

As BCI matures, this technology raises important legal and ethical questions. Amid the rapid advancement of BCI technologies, a growing discourse emerges around the necessity for "neurorights," or rights specifically designed to protect the neural data and cognitive liberty of individuals. However, even as calls for neurorights gain momentum, there remains a foundational need to address basic regulatory issues.

One of the primary questions is whether these BCI devices should be included in existing regulatory frameworks like the Medical Devices Regulation of the European Union (EU MDR) or the AI Act or even the AI Product Liability Directive, to the extent AI is used/is an integral (safety) component of the device. The critical task at hand is to accurately assess whether BCIs fall within the scope of the MDR, especially with regard to the nuanced differentiation between BCIs developed for medical purposes and those intended for human enhancement.

BCIs intended for medical purposes are those designed to prevent, diagnose, monitor, treat, or alleviate health conditions. They are often developed with the goal of restoring lost functions due to injury or disease, such as mobility in paralysis, auditory perception with cochlear implants, or communication abilities for individuals with ALS. These applications fall within the definition of medical devices and are subject to stringent regulatory frameworks like the EU MDR. In 2021, the U.S. Food and Drug Administration (FDA) issued guidance, Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation – Non-clinical Testing and Clinical Considerations, to provide recommendations for nonclinical testing and study design considerations for Investigational Device Exemptions (IDEs) feasibility and pivotal clinical studies for BCI devices for patients with paralysis or amputation.

In contrast, BCIs for enhancement are developed to augment, improve, or extend human capabilities beyond what is considered the typical or baseline state of health. This can range from cognitive enhancement, such as improving memory or learning capabilities, to augmenting physical abilities or sensory experiences. Enhancement BCIs venture into the realm of optimizing human performance and experience — so in healthy individuals and not in response to or for diagnosis of a health condition — rather than addressing medical needs. These applications raise unique regulatory challenges as they do not fit neatly into existing regulatory frameworks (notably those for medical devices) and are also not (yet) covered by

the group of devices *without an intended medical purpose* according to EU MDR Annex XVI to which requirements under the EU MDR applies. Enhancement BCIs are, at the moment, lacking a defined regulatory path in most many jurisdictions (notably, Chile is the first country in the world to legislate on neurotechnologies and included "brain rights" in its constitution).

In addition, regardless of qualification as a medical device, such tools may nevertheless be subject to other complex frameworks such as the EU AI Act, if they encompass such technology.

As BCI technology continues to evolve, so will the frameworks for regulating and governing their use. For companies embarking on or considering the development of BCI technologies, particularly those focused on human enhancement, taking into account three core tasks is crucial:

1. **Stay informed on regulatory developments.** Monitor updates and changes in regulations relevant to BCI technologies, such as the EU MDR and its Annex XVI and any relevant Commission implementing acts/Medical Device Coordination Group (MDCG) guidance, which covers devices without an intended medical purpose. Understanding these regulations can help anticipate compliance requirements and adapt development processes accordingly.
2. **Engage with regulatory bodies early and continuously.** Initiating dialogue, either directly or through industry associations, with regulatory authorities at the early stages of technology development helps to facilitate a smoother navigation through compliance requirements and influence the development of regulations and their execution. Continuous engagement can also offer insights into regulatory trends and expectations, for instance around the crucial topic of timely and adequate data generation. If the right type of data (e.g., on safety/efficacy) has not been collected throughout development, the resulting data gaps may be much more difficult to remedy after the deployment or during certification of the device, which can be costly and result in delays for the companies.
3. **Prioritize safety and ethics.** Adopt stringent safety protocols and ethical standards from the outset. This approach not only ensures regulatory compliance but also builds consumer trust and positions your company as a responsible innovator.