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Ambiguities in Neurotech Regulation

Breakthrough neurotechnologies have the potential to help patients suffering from a range of diseases—if regulators can ensure these devices serve those who need them most.

Emerging technologies for health care, such as brain-computer interfaces (BCIs), offer hope to people suffering from myriad neurological diseases and disorders, including depression, Parkinson's disease, and Alzheimer's. These conditions have been uniquely difficult to treat because of complexities that include the blood-brain barrier (which helps protect the brain from harmful toxins and pathogens in the bloodstream), the intricacy of the nervous system, and the obscure nature of the human mind. Further, mental health conditions often lack easily measured biomarkers like heart rate or blood glucose levels that can be used to assess treatments for other diseases. Neurological maladies cost the United States an estimated $800 billion per year and place incalculable emotional and financial burdens on patients, caregivers, and loved ones; the possibility of new, effective treatments is more than welcome.

Despite their promise, the breakthrough neurotechnologies that are in development face a critical barrier: the growing gap between innovations and the current policy for regulating and managing medical devices. If this gap is not bridged, misguided use could cause harm and even spur public backlash against BCIs and similar technologies. Before more BCIs enter the market, policymakers must find ways to close this rift.

A recent legal battle illustrates the gray area in medical device regulation, which could foreshadow issues with neurotechnologies. In 2021, the US Court of Appeals for the District of Columbia Circuit overturned a ban the US Food and Drug Administration (FDA) had put on the use of wearable devices that deliver painful electric shocks intended to modify self-harming or aggressive behaviors. The FDA issued the ban in 2020, after six years of deliberation, against a specific use of electric shock devices by a school in Massachusetts. For years, disability rights activists had protested the Judge Rotenberg Educational Center, a residential school that reportedly used these devices frequently to deter behavior by students with autism and other conditions. After a court case used a 2012 treatment video from the facility showing a child crying and begging to not be shocked, only to be shocked into a catatonic state, the video went viral. In 2013, the United Nations Human Rights Council issued a report declaring the practice violated rights on freedom from torture.

In its 2020 ban, the FDA argued that using "electrical stimulation devices for self-injurious or aggressive behavior" presented an "unreasonable and substantial risk of illness or injury." Relying on its federal authority to keep dangerous devices from the market, it banned this application, citing physical and psychological risks "including worsening of underlying symptoms, depression, anxiety, post-traumatic stress disorder, pain, burns and tissue damage." The school insisted that the benefits to its patients far exceeded the risks and filed suit, arguing that the school's doctors should be allowed to select the treatment option they felt was best.

Subsequently in 2021, the DC Circuit Court, in a two-to-one ruling, held that the FDA's "use-specific" ban "interferes with a [medical] practitioner's authority by restricting the available range of devices through regulatory action." According to this argument, the school's use represented the "practice of medicine" and so was outside the FDA's authority.

Before this ruling, so-called off-label use—when health care providers prescribe pharmaceuticals or medical devices for something other than what the FDA's authorization covers—had not been particularly controversial. After the FDA has determined the basic safety of treatments, allowing physicians to manage off-label use under their authority to practice medicine can help bring treatments to patients. And for patients with complex conditions that cannot be tested directly in clinical trials, the practice has been beneficial. However, as the opinion written by Sri Srinivasan, the dissenting judge from the DC Circuit Court, suggests, an extreme interpretation of this approach—where the FDA cannot step in to prevent specific, harmful off-label uses—lacks crucial flexibility. Given that the FDA could ban the device outright for all uses, Srinivasan argued, it was "hard to perceive why Congress could want to deny the agency that middle-ground option."

Going forward, this lack of a middle ground could hinder the government's ability to properly regulate medical devices. Besides the option of banning devices, it leaves decisions about safety, risk, and clinical utility to individual health care practitioners or their organizations. The more complex and powerful the medical device, the more concerning this is.

In this regard, BCIs are of particular concern. These devices connect the user's brain to a computer—and some could require invasive surgery—to interpret, respond to, or change brain activity. Current devices target conditions such as paralysis, epilepsy, and depression. But rulings like the recent DC Circuit Court's leave the door open for a BCI device to gain FDA approval for a narrow indication, like a severe physical impairment, only to be applied more broadly, such as for behavioral modifications or even cognitive enhancement—without any formal assessment of risks and benefits.

Although BCI treatments for mental illness could potentially help patients, poorly regulated off-label uses may also unveil potential harms and controversies. Disability rights groups argue that electroshock interventions to "treat" behaviors perceived as socially problematic are abusive and violate human rights. Neurodiversity poses another conundrum: parents, physicians, and societies continue to debate whether autism spectrum and attention-deficit/hyperactivity disorders are diseases requiring treatment or neuroprocessing differences that demand respect. After all, nonheteronormative sexual orientations and gender identities were long considered mental illnesses. And in some cases, gay men were enrolled in studies that used electroshock treatments designed to cause pain in what was called "aversive conditioning."

BCIs could soon offer unprecedented access to the human mind, and policies surrounding them require immediate attention. First, Congress should enact legislation to give the FDA clear authority to regulate and even ban "single-use" applications of BCIs, given the unique challenges of off-label use. This would give the FDA tools to erect safeguards around potentially harmful or marginalizing uses of powerful devices without drastically expanding the agency's authority.

For particularly vulnerable people, including children and those with intellectual disabilities, policymakers could require some level of informed consent to BCI use, both directly and from caretakers. Colorado has already lowered the age to consent to psychotherapy without a parent or guardian, for example, reflecting a desire to empower young people to make their own decisions about treatments. Federal and state legislatures should also consider policies to regulate the use of BCI devices within schools and other contexts involving children.

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Lastly, health care professional societies and state licensing boards should set standards of care and codes of conduct that guide medical practice and inform malpractice claims.

Ultimately, realizing the vast potential of BCIs to alleviate suffering from neurological disease and mental illness may depend on careful policies to ensure these devices best serve those who need them most. Safe and responsible development of BCIs should include honest discussions about the gaps in regulatory authority over specific uses and particularly vulnerable patients, especially when treatments are to curb behaviors perceived as socially unacceptable rather than to reduce individual suffering.

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