VIEWPOINT

Protecting Neural Data Privacy—First, Do No Harm

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A Revolution in Neurotechnologies

Jumpstarted by the US BRAIN Initiative launched by President Barack Obama in 2013, advances in neurotechnologies, defined as methods to monitor or alter the activity of the nervous system, have outpaced regulatory governance at all levels.[1] Such advances in neurotechnologies in the last 2 years alone include deeper capabilities to enhance working and long-term memory[2] to decode high-resolution mental imagery from functional magnetic resonance imaging data[3] and the reconstruction of internal language from noninvasive brain recordings.[4] At scale, recent years have also seen the proliferation of consumer neurotechnology devices, with now some 30 on the market, collecting neural data[5] with promises such as to enhance cognition, improve sleep, deepen meditative states, and balance mood, among other indications. Furthermore, companies, such as Meta, Apple, Snap, and Neuralink, have each patented or are developing wearable neurotechnologies that will soon enter the market at world population levels never seen before. Our concerns lie with the latter 2 categories, which remain essentially without any regulation.

Indeed, while these technologies, especially brain-computer interfaces, as noted by the Institute of Electrical and Electronics Engineers neuroethics framework,[6] promise the capability to fundamentally alter how we diagnose and treat neurologic and mental diseases, as well as how broader societies function, they also pose unprecedented ethical dilemmas. Human rights issues, such as mental privacy,[7] fair access to augmentation, freedom from bias, preservation of personal identity, and free will, all remain at the center of ethical debates as we enter the age of neurotechnology.

The time is right for the clinical neurology community to act, first by supporting state laws for protecting mental privacy. This may be achieved through efforts, such as those that recently succeeded for the first time in Chile, the State of Rio Grande do Sul in Brazil, and Colorado, and are underway in California, Minnesota, Illinois, Mexico, Colombia, and Uruguay.

From the Clinic to the Consumer Market

Patients deserve the best diagnostic and therapeutic tools available. Furthermore, they remain a critical bottleneck of our clinical practice. While devices and treatments, such as those advances first mentioned, approved by the US Food and Drug Administration (FDA), remain the gold standard, neurologists are faced with an increasing market of consumer devices that promise the same clinical benefits and use technology with a level of sophistication as those with FDA approval—and yet, exist in an environment for patients without the same strict data protections.

At the time of this writing, there are at least 30 such unregulated devices on the consumer market, primarily headsets and headbands, collecting medical-grade electroencephalogram or similar data, which differ from other grades of neural data due to their clinical implications. Indeed, these consumer devices have been used in hundreds of National Institutes of Health–funded research studies and while these studies' data should be shareable so as to replicate results, these consumer devices possess the capability to diagnose anxiety, stroke, epilepsy, sleep disorders, mild cognitive impairment, and others.

The Lack of Legal Protection for Consumer Neural Data

Even though they gather and analyze medical-grade neural data, consumer neurotechnology devices are unregulated and consumer brain data remain unprotected. In April 2024, the Neurorights Foundation, a US nonprofit organization, published its report.[8] The report reviewed the user agreements of the products of 30 such companies and benchmarked them against 6 global consumer data privacy standards across 5 thematic areas of concern, including access to information, data collection and storage, data sharing, user rights, and data safety and security. Across these 5 areas, broad gaps between these standards and actual data practices emerged. For example, 29 of the 30 companies have access to the consumer's neural data and provide no meaningful limitations on access. Almost all the companies can share data with third parties. User rights, such as withdrawing consent to data processing and requesting data deletion, are not uniformly extended.

Current State of Advocacy and Strategy for Neural Data Protection

On April 17, 2024, Governor Jared Polis of Colorado signed the first piece of legislation in the world to legally define and protect neural data as sensitive, extending the protections of the Colorado Privacy Act. The bill was introduced by State Representative Cathy Kipp (D, Fort Collins) and achieved bipartisan support in both chambers, passing the Colorado House of Representatives on a vote of 61-1, and unanimously in the Senate, 34-0. In a strategy spurred by the clinical neurology community, the Colorado Medical Society, supported by the Neurorights Foundation, adopted in-house policy on mental privacy prior to legislative action, giving Representative Kipp practical backing to pursue legislative solutions—a replicable framework for advocacy across the country. Indeed, a similar bill, has been put forth in California and was unanimously approved by both chambers and signed into law by Governor Gavin Newsom on September 30, 2024.

Meanwhile, at the federal level, there is a bipartisan and bicameral bill called the American Privacy Rights Act, which is being advanced by the respective chairs of the US Senate and US House Commerce committees. A revised draft of the bill published in June 2024 now explicitly provides protection for neural data. It remains uncertain, given unrelated complexities of the bill, whether it will have the

support to be adopted by this Congress. Nonetheless, the adoption of neural data protection in state consumer privacy laws will only strengthen the potential of an ultimate federal precedent.

Time to Act: How and Where Neurologists Can Use Neural Data Privacy Legal Strategy

The neurology community stands poised to encourage the replication of such efforts, first by approaching state legislators and working in teams with medical societies and nonprofit organizations in 13 states with consumer privacy laws in progress, including Massachusetts, New York, Pennsylvania, Alaska, Georgia, Louisiana, and others. And there are 18 additional states that either have or will soon have amendable comprehensive privacy laws, including Virginia, Connecticut, Indiana, Tennessee, Kentucky, Iowa, Nebraska, Oregon, Utah, Montana, Texas, Delaware, Florida, New Jersey, Maryland, Minnesota, Rhode Island, and New Hampshire. As it will be our patients who are impacted most by these extraordinary advances in the age of neurotechnology, we owe them our unified legislative support toward the assurance that their neural data will enjoy the same protections as consumers and private citizens as they do in the examination room.

Through the teamwork of neurologists, legislators, medical associations, such as the American Medical Association, and human rights organizations with legal expertise, we stand the best chance of realizing the benefits of these amazing new tools as they change the lives of patients and the world—and minimizing the risks of neurotechnologies being misused or abused. The time for neurologists to act is now.

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