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RESEARCH

The Illusion of Distinction in 'Neural Data' Governance: Rethinking United States Consumer Data Protections Through a European Lens

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Abstract Neurotechnology-derived data faces increasing challenges due to the lack of salient policy and regulatory guidance. Current legal frameworks produce inconsistencies in how data is regulated, which constrains both harmonization and standardization in the consumer domain. This Article begins by reviewing the current state of data protections in the United States that are relevant to consumer neurotechnology. It then examines the safeguards available within the European Union. As part of our comparative analysis, we assess how these legal frameworks apply to neural data collected by 47 different consumer neurotechnology wearables from 30 different companies. Our findings indicate that discrepancies in the definition of 'neural data' lead to differing levels of protection. Given that consumer neurotechnologies readily cross borders, such discrepancies may leave consumers exposed to devices developed under weaker protections, reinforcing the need for at least partial regulatory alignment. While

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establishing a universal definition of 'neural data' is conceptually appealing, we argue that it should not distract from the broader issues that give rise to the need for such a definition in the first place. Ultimately, our research suggests that policymakers may be better served by regulating the outcomes of data use rather than focusing exclusively on the data's origin. Such an approach could better address the tension between promoting innovation, protecting individual rights, and ensuring product safety.

Keywords Consumer neurotechnology · Direct-to-market · Neural data · Non-neural data · Technological risk · Data protection · Privacy regulation

Neurotechnology innovation is increasingly moving into the consumer realm. Though still primarily used in research and clinical care, a growing number of companies are marketing devices such as non-invasive brain–computer interfaces, wearables, and neuromonitoring headsets directly to consumers [1]. These products are used for a range of purposes, including self-administered mental health treatment, cognitive enhancement, well-being, and entertainment [2]. Sensors may detect both environmental and physiological changes, which are algorithmically processed for device use, often without the data provider's full understanding. Many scholars have identified significant gaps in existing regulatory frameworks and questioned their applicability to neurotechnologies [3]. The rapid development of the field has also led interdisciplinary experts from various international consortia to call for the ethical use of neurotechnology, including the regulation and governance of 'neuronal data', 'brain data', or 'neural data' [4–6]. However, while there is broad agreement that data collected by neurotechnologies should be regulated, it remains unclear how such data fit within existing data governance frameworks.

Contributing to this challenge is the lack of shared terminology among specialists. Experts across disciplines conceptualize neurotechnology-derived data at different levels of analysis, depending on their respective interests. A molecular scientist or immunologist, for instance, may be interested in collecting stable and dynamic information from the nervous system related to physiological processes. Their work could involve collecting small-scale recordings derived from individual neurons, groups of axons, or clusters of neuronal cell bodies (e.g., patch-clamp recordings, calcium imaging, etc.) from the cerebrum, cerebellum, brainstem, or peripheral nerves. The individuals doing this work may refer to 'neuronal data' [7] or related terms, such as 'glia-secretome data' [8] or 'neuroendocrine data' [9]. By contrast, a neuropsychologist or psychiatrist may be concerned with patterns of activity, morphology, or cognitive function associated with the nervous system. Their work could involve collecting large-scale recordings related to the brain's structure or function (e.g., diagnostic neuroimaging) from the cerebrum. The individuals doing this work may prefer the terminology of 'brain data' [10] or 'neuroimaging data' [11]. Each term implies a different understanding of the limits and possibilities of what the data can support.

It appears that the term 'neural data' has become the preferred expression among regulators, legislators, and policymakers in the United States (US) and several international contexts. However, it does not have a uniform definition across disciplines and is often employed ambiguously, with little specification of its intended scale, scope, or ontological status [12]. Some scholars have sought to clarify the meaning of 'neural data,' suggesting that it should not be understood merely as bodily data, but rather as encompassing phenomena related to neurocognitive states, processes, and structures [13]. From this perspective, 'neural data' is less about the structure of the nervous system than about the representation or replication of information unique to cognitive architecture, thus, extending into the domain of the 'mind' [13]. Some have even proposed the alternative notion of 'cognitive biometrics' to capture the informational and identity-bearing dimensions of such data [13, 14]. Yet, it remains uncertain whether current governance frameworks (or those advocating for 'neural data' regulation) share this expansive conceptualization. As we will discuss in this Article, early evidence suggests that they do not.

Our Article examines how data collected and processed by consumer neurotechnologies are regulated across different jurisdictions. We build on recent US-focused policy mapping efforts [15] by extending discussions of post-BRAIN Initiative neurotechnology governance to European regulatory frameworks.

Our comparative analysis is not intended to be exhaustive. Rather, we focus on a select few jurisdictions in the US and the European Union (EU) to illustrate how attempts to distinguish between neural and non-neural data can result in fragmented (and potentially incoherent) neurotechnology governance frameworks.

Methodology

Our study employed a functionalist comparative methodology to examine the regulatory treatment of consumer neural data in the US and the EU [16]. The comparative design was exploratory and problem-driven, motivated by an initial observation that the two jurisdictions appear to be developing divergent responses to a neurotechnology-derived data: in the US, state-driven definitional experimentation is occurring within a comparatively underdeveloped federal data protection framework, and in the EU, a general data protection framework dominates across Member States with relatively limited definitional fixation. Against this backdrop, we analysed how each jurisdiction structures, or omits to structure, the distinction between neural and non-neural data. A comparative approach was deemed helpful because it allows for the examination of how different legal systems address substantively similar governance problems [16]. Both of the selected jurisdictions currently constitute the world's largest commercial markets for consumer neurotechnology products, [17][1] and face the risk of fragmented governance due to (Member) State autonomy [18].

Rather than limiting our analysis to instruments explicitly framed as attempting to govern "neurotechnology," instruments were selected on the basis of their substantive implications for the development, deployment, or oversight of neurotechnologies, or the data they generate. This approach is particularly useful in the context of cross-sectoral emerging technologies, where the relevant governance mechanisms may not yet be organised under a coherent or technology-specific framework [19]. Accordingly, we examined US laws and regulatory frameworks, alongside their EU counterparts. Professional association standards and soft-law instruments were also considered, particularly where these are intended to guide industry practices or offer guidance on the development of neurotechnology policy. Our analysis of the European regulatory landscape does not systematically examine Member State legislation or deontological governance initiatives. This methodological choice partly reflects the composition of the author team, whose expertise is primarily concentrated in the US. Accordingly, we elected to focus on EU-level instruments that establish common regulatory baselines across the Union and are most relevant to the comparative objectives of this study.

We compared the selected governance instruments by assessing their treatment of consumer neurotechnology products and platforms. Our approach was inspired by a pragmatic legal research philosophy [20]. Comparative analysis of concrete technological applications allows researchers to examine how abstract legal standards operate when applied to real-world technologies, rather than limiting comparison to formal statutory language or doctrinal structure. Accordingly, the analytical sample was restricted to the 30 consumer neurotechnology companies identified in an existing catalogue [21]. The product-level review then identified consumer neurotechnology products, platforms, or product-level entries associated with those companies through publicly available materials. Although this catalogue is less extensive than more recent market-mapping efforts that identify over 250 neurotechnology companies [17], it nonetheless encompasses companies offering a diverse range of consumer-facing device and platform types. These include single-sensor and mixed-signal systems marketed for wellness, cognitive enhancement, entertainment, sleep, meditation, and neurofeedback. The sample was thus illustrative, rather than statistically representative, of the entire consumer neurotechnology market. Our aim was to conduct an exploratory analysis of how current governance frameworks respond to consumer neurotechnology products and associated data practices, rather than to provide a comprehensive market assessment.

[1] The report found that 48% of consumer neurotechnology firms surveyed were from North America ($n = 131$, U.S. with 117, Canada with 14), while 38% were from the European Union ($n = 103$). The ratio of consumer to medical firms was 0.54:0.46 for North America and 0.58:0.42 for the European Union. While both ratios were high, in North America, devices were mainly used for wellness, or consumer electronics for entertainment, whereas in the European Union devices were mainly used for R&D, or neurotechnology software. North American firms were mainly funded through venture capital, whereas those in the European Union were mainly funded though public sources.

When conducting the product-level review of selected companies, we reviewed publicly available materials to identify consumer neurotechnology products, platforms, or product-level entries associated with those companies (May 2026). Sources included official company materials, such as product pages, FAQs, privacy policies, terms of use, app-store descriptions, and company-issued technical documentation. Where documentation was limited, additional publicly available materials were cautiously used to clarify product availability or technical characteristics. These included app-store listings, retailer specifications, archived product pages, product manuals, regulatory or certification listings, and reputable media or review articles. For each product or platform, we extracted recorded data modalities and real-time streaming capabilities. "Real-time" was defined as the availability of live data through in-app feedback or streaming interfaces, and did not necessarily imply access to raw sensor data. We also noted whether products appeared to rely on classical algorithmic processing or artificial intelligence (AI) approaches, and whether they offered open developer access through software development kits (SDKs), application programming interfaces (APIs), or related interfaces. These features are relevant because any governance problem would not be limited to the initial collection of neural or non-neural signals. Our process yielded 47 product-level entries for comparative analysis.

Each product-level entry was analysed against both jurisdictions' regulatory frameworks to assess how it would plausibly be classified under each governance instrument included in the study, taking into account product marketing claims, technical characteristics, data modalities, intended use, and relevant statutory definitions. To ensure transparency and reproducibility, a three-point coding scheme was applied to each product–instrument pairing: "Yes," "Unclear," or "No". "Yes" was used where the available legal and product-level information supported a plausible positive assessment of coverage. "Unclear" was reserved for cases in which either the statutory scope or the available product information did not support a sufficiently confident assessment. "No" was used where the available information indicated that the relevant product or data stream would fall outside the scope of the instrument. This coding reflected the legal plausibility that a governance instrument would apply to the data emerging from a given product or platform as marketed.

For product-regulation frameworks such as the *FDCA*, particular weight was given to intended use, as reflected in product labelling, manufacturer representations, and marketing claims, rather than to technical capability alone. For mixed-data products and platforms, the classifications do not imply that the entire product is wholly covered or wholly excluded from a given framework. Rather, they reflect whether the relevant statutory definition plausibly reaches the neural data collected or inferred by the product, and whether associated physiological, behavioural, contextual, or inferential data streams appear to fall inside, outside, or ambiguously within that same framework.

Analysis

Consumer neurotechnology products and platforms may rely on a variety of data modalities (Table 1). Our product-level comparison revealed that the majority of the reviewed products and platforms (33 of 47) were multimodal in nature, integrating neural, biosignal, and contextual or behavioural data streams (Table 2). These combinations commonly included EEG or fNIRS, alongside motion sensing, cardiac or respiratory signals, eye-related measures, app-derived metrics, cognitive or training scores, and session analytics. Nearly all products and platforms (44 of 47) supported real-time data streaming or feedback, although this did not necessarily imply access to raw neural data. A substantial proportion of products and platforms (29 of 47) also provided open developer access through software development kits, application programming interfaces, or related interfaces, indicating that data processing and reuse may extend beyond manufacturer-controlled applications. By contrast, for most products and platforms (34 of 47), no publicly available information was identified during the search that clearly specified whether AI/ML approaches were used at the product level. Across the dataset, products developed by the same company generally exhibited highly similar technical and functional profiles. This is unsurprising given that firms typically rely on shared analytical pipelines and established modalities across product lines once such capabilities are developed. Accordingly, in subsequent product-instrument assessments, results are presented at the company level; this aggregation reflects the substantial similarity observed across products within the same firm, rather than any assumption that all activities within a given company are uniformly within or outside regulatory scope (Table 3).

Table 1 Categories of existing data modalities used by consumer neurotechnology products and platforms

Category	Symbol	Sensor / Signal Examples	Purpose
Neural	N	Electroencephalography (EEG), Functional Near-Infrared Spectroscopy (fNIRS)	Record electrical or hemodynamic activity of the brain.
Biosignal	B	Heart Rate (HR), Heart Rate Variability (HRV), Photoplethysmography (PPG), Electromyography (EMG), Electro-oculography (EOG), Galvanic Skin Response (GSR), SpO_2 (Peripheral capillary oxygen saturation)	Measure direct physiological activity from the body (cardiac, muscular, ocular, or autonomic).
Contextual/Behavioral	C	Inertial Measurement Unit (IMU), Accelerometer, Gyroscope, Global Positioning System (GPS), Optical and camera-based eye-tracking, Microphone (mic), Application metrics, Cognitive test scores	Capture motion, orientation, or environmental context rather than physiological signals.

The table outlines three potential categories of data modalities that may be used by consumer neurotechnology products and platforms, providing examples of associated sensors and signals, as well as the primary rationale for using each

We evaluated eleven regulatory and evaluative frameworks. First, we examined the US regulatory landscape governing neurotechnology devices, followed by an analysis of the legal treatment of data generated by such devices. This included an assessment of the *Federal Food, Drug, and Cosmetic Act* (FDCA) [22], as well as state-level data protection statutes in Colorado, California, Montana, and Connecticut addressing neurotechnology-derived data. We also considered emerging federal legislative initiatives addressing the commercial use of 'neural data,' including instruments that may draw upon external sources as persuasive authority. In this context, we highlighted the American Medical Association's *Resolution 503, Safeguarding Neural Data Collected by Neurotechnologies* [23], and the proposed *Management of Individuals' Neural Data Act of 2025* (MIND Act of 2025) [24]. These developments were further considered alongside the potential implications of conflicting executive order directives (EOs), which may introduce additional uncertainty into neurotechnology governance.

Our analysis then considered the EU regulatory framework, including the *Medical Device Regulation* (MDR) [25], the *General Data Protection Regulation* (GDPR) [26], the *General Product Safety Regulation* (GPSR) [27], and the *EU Artificial Intelligence Act* [28], with respect to both device-level regulation and the governance of neurotechnology-derived data.

While several of the frameworks lacked direct functional equivalents across jurisdictions, each nevertheless addressed salient dimensions of neurotechnology governance. Our assessment identified substantial inconsistencies across the selected frameworks, particularly with respect to the definition and scope of legal protection afforded to neurotechnology-related data (Table 4).

The Current State of Consumer Protection for Neurotechnology Wearables in the US

Current Federal Product Regulation

A consumer neurotechnology wearable that is considered a medical device would be regulated by the Food and Drug Administration (FDA) under the *FDCA*. This set of laws intends to protect US citizens from harmful products that may be unsafe or ineffective. It is meant to primarily provide upfront regulatory oversight, as opposed to post-market data protection.

Table 2 Current technological features of selected consumer neurotechnology products and platforms

Product/platform (company)	Data modalities		Real-time stream	AI/ML claim at product level	Open developer access
Bía Smart Sleep Mask (Bía Neuroscience)	fNIRS; temperature sensor; microphone; ambient light sensor; accelerometer; app-derived sleep metrics	N B C	Unclear	Unclear	No
HALO Headband (BrainAccess)	EEG; 3-axis accelerometer; real-time EEG streaming and external synchronization supported through software ecosystem	N C	Yes	Unclear	Yes
MINI Kit (BrainAccess)	EEG; real-time EEG streaming and external synchronization supported through software ecosystem	N	Yes	Unclear	Yes
MIDI Kit (BrainAccess)	EEG; real-time EEG streaming and external synchronization supported through software ecosystem	N	Yes	Unclear	Yes
MAXI Kit (BrainAccess)	EEG; real-time EEG streaming and external synchronization supported through software ecosystem	N	Yes	Unclear	Yes
BrainBit Headband (BrainBit)	EEG	N	Yes	Unclear	Yes
BrainBit Flex / Flex 4 (BrainBit)	EEG	N	Yes	Unclear	Yes
BrainBit Flex8 (BrainBit)	EEG	N	Yes	Unclear	Yes
FRENZ Brainband (Earable Neuroscience)	EEG; EOG; EMG; SpO_2; heart rate; breathing rhythm; head motion; app analytics	N B C	Yes	Yes	Unclear
EPOC X (EMOTIV)	EEG; 9-axis motion sensor	N C	Yes	Unclear	Yes
Insight 2 (EMOTIV)	EEG; 9-axis motion sensor	N C	Yes	Unclear	Yes

Table 2 (continued)

Product/platform (company)	Data modalities		Real-time stream	AI/ML claim at product level	Open developer access
Flex 2 (EMOTIV)	EEG; 9-axis motion sensor; EEG/ECG/EMG/EOG acquisition supported depending on setup	N B C (configuration- dependent)	Yes	Unclear	Yes
Flow tDCS Headset + Flow App (Flow Neuroscience)	Transcranial direct current stimulation (tDCS); app-guided treatment sessions; depression symptom tracking through MADRS questionnaire; treatment adherence and outcome monitoring through clinician platform	C	No	Unclear	No
Flowtime Biosensing Meditation Headband (Flowtime)	EEG; HRV; breathing; app-derived meditation metrics	N B C	Yes	Unclear	No
FocusCalm EEG Headband + App (FocusCalm)	EEG; app exercise, game, and meditation data	N C	Yes	Yes	No
Healium Biofeedback Meditation Platform (Healium)	External EEG via compatible headbands; heart-rate/smartwatch data via compatible devices; VR/AR and app/session metrics	N B C (integration- dependent)	Yes	Unclear	No
iBand+ EEG Headband (iBand+ / Arenar B.V.)	EEG; body-movement sensor; app-level sleep analytics	N C	Yes	Yes	No
IDUN Guardian Earbuds IGE-3.1 (IDUN Technologies)	In-ear EEG; IMU/motion sensing; real-time classifiers, including jaw-clench and eye-movement outputs	N C	Yes	Unclear	Yes
IDUN Guardian 4 Starter (IDUN Technologies)	In-ear EEG; IMU/motion sensing; cloud/webapp/API; real-time classifiers	N C	Yes	Unclear	Yes
BrainLink Lite (Macrotellect)	EEG brainwave data; Bluetooth/app-based EEG outputs	N	Yes	Unclear	Yes

Table 2 (continued)

Product/platform (company)	Data modalities		Real-time stream	AI/ML claim at product level	Open developer access
BrainLink Pro (Macrotellect)	EEG brainwave data; Bluetooth/app-based EEG outputs; additional sensors not confirmed at product level	N	Yes	Unclear	Yes
BrainLink Tune (Macrotellect)	EEG brainwave data; app-based focus/relaxation and Pomodoro/session outputs	N C	Yes	Unclear	Unclear
Smarting S (mBrainTrain)	EEG; LSL/software-based streaming and synchronization support	N	Yes	Unclear	Yes
Smarting PRO (mBrainTrain)	EEG; LSL/software-based streaming and trigger synchronization support	N	Yes	Unclear	Yes
Smarting PRO X (mBrainTrain)	EEG; LSL/software-based streaming support	N	Yes	Unclear	Yes
Mendi Headset (Mendi)	fNIRS; app/game and training-progress metrics	N C	Yes	Unclear	No
Muse 2 (Muse / InteraXon)	EEG; heart rate; breath-related measurements; body movement; app session metrics	N B C	Yes	Unclear	Yes
Muse S Athena (Muse / InteraXon)	EEG + fNIRS; heart-rate and breath monitoring; body movement; app-derived coaching/metrics	N B C	Yes	Unclear	Yes
Myndlift Remote Neurofeedback Program (Myndlift)	External EEG through compatible Muse devices; cognitive tests; symptom questionnaires; app/session metrics	N C (integration- dependent)	Yes	Unclear	No
MyndBand BLE EEG Brainwave Headset (MyndPlay)	EEG; Bluetooth/mobile/VR integration; app states such as focus/relaxation/mindfulness	N C	Yes	Unclear	Yes

Table 2 (continued)

Product/platform (company)	Data modalities		Real-time stream	AI/ML claim at product level	Open developer access
Myneurva At-Home Neurofeedback Program / BrainStation (Myneurva)	19-sensor EEG/QEEG brain scan; remote neurofeedback sessions; QEEG report; neurofeedback analysis, reporting, and support	N C	Yes	Yes	No
Narbis Neurofeedback Smart Glasses (Narbis)	EEG/brainwave sensing; tablet/app session data and training outputs	N C	Yes	No	No
SenzeBand 2 (Neeuro)	EEG; PPG; 9-axis motion sensing; app/software metrics	N B C	Yes	Yes	Yes
Neuphony EEG Headband (Neuphony)	EEG; mobile/desktop neurofeedback metrics	N C	Yes	Yes	Yes
MW75 Neuro (Neurable)	EEG; app-derived focus, productivity, and cognitive-state reports	N C	Yes	Yes	No
MW75 Neuro LT (Neurable)	EEG; app-derived focus, productivity, cognitive strain, recovery, brain-age, and related cognitive-state reports	N C	Yes	Yes	No
Neuradiant / Neuronic LIGHT (Neuronic)	1070 nm near-infrared transcranial photobiomodulation; app-connected or controller-guided stimulation protocols; user profiles/session protocol information	C	Unclear	Unclear	No
NeurOptimal® Neurofeedback System (NeurOptimal)	EEG-based brain-activity monitoring; proprietary software/session metrics	N C	Yes	Unclear	No
Crown (Neurosity)	EEG; app/dashboard/API performance metrics	N C	Yes	Unclear	Yes

Table 2 (continued)

Product/platform (company)	Data modalities		Real-time stream	AI/ML claim at product level	Open developer access
MindWave Mobile 2 (NeuroSky)	EEG; derived Attention, Meditation, Eye Blink, and BandPower metrics through the ThinkGear ecosystem	N	Yes	Unclear	Yes
Galea (OpenBCI)	EEG; EMG; EDA; PPG; eye tracking; XR/VR integration	N B C	Yes	Unclear	Yes
Cyton Biosensing Board (OpenBCI)	EEG/EMG/ECG depending on configuration; accelerometer data supported; software-dependent integration	N B C (configuration- dependent)	Yes	No	Yes
Ganglion Board (OpenBCI)	EEG/EMG/ECG depending on configuration; accelerometer data supported; software-dependent integration	N B C (configuration- dependent)	Yes	No	Yes
Sens.ai Brain Training Headset (Sens.ai)	EEG / ERP methods advertised; HRV biofeedback; app missions, assessments, and training outcomes	N B C	Yes	Unclear	No
Unicorn Hybrid Black (Unicorn / g.tec)	EEG; 3-axis accelerometer; 3-axis gyroscope	N C	Yes	No	Yes
Unicorn BCI Core-8 (Unicorn / g.tec)	EEG; 1000-Hz option marketed as suitable for ECG/EMG recordings; software/SDK streaming support	N B (configuration- dependent)	Yes	No	Yes
URGOnight (URGOTECH)	EEG headband + mobile sleep-training app	N C	Yes	Unclear	No
Overview	—	14 Single Data, 33 Multimodal Data	44 Yes, 2 Unclear, 1 No	8 Yes, 34 Unclear, 5 No	29 Yes, 2 Unclear, 16 No

The table summarizes 47 consumer neurotechnology products, platforms, or product-level entries according to recorded data modalities, real-time streaming or feedback capabilities, algorithmic approaches, and developer-access options. *N* Neural; *B* Biosignal; *C* Contextual/Behavioral (see Table 1)

Table 3 Grouping of selected neurotechnology products and platforms by company for comparative legal framework analysis

Neurotechnology Company	Product/Platform(s)	Reference
Bía Neuroscience	Bía Smart Sleep Mask	Bía
BrainAccess	HALO Headband, MINI Kit, MIDI Kit, MAXI Kit	BrainAccess
BrainBit	BrainBit Headband, BrainBit Flex / Flex 4, BrainBit Flex8	BrainBit
Earable Neuroscience	FRENZ Brainband	Earable
EMOTIV	EPOC X, Insight 2, Flex 2	Emotiv
Flow Neuroscience	Flow tDCS Headset + Flow App	Flow
Flowtime	Flowtime Biosensing Meditation Headband	Flowtime
FocusCalm	FocusCalm EEG Headband + App	FocusCalm
Healium	Healium Biofeedback Meditation Platform	Healium
iBand+ (by Arenar B.V.)	iBand+ EEG Headband	iBand
IDUN Technologies (Guardian / Dryode)	IDUN Guardian Earbuds IGE-3.1, IDUN Guardian 4 Starter	IDUN
Macrotellect	BrainLink Lite, BrainLink Pro, BrainLink Tune	Macrotellect
mBrainTrain	Smarting S, Smarting PRO, Smarting PRO X	mBrainTrain
Mendi	Mendi Headset	Mendi
Muse	Muse 2, Muse S Athena	Muse
Myndlift	Myndlift Remote Neurofeedback Program	Myndlift
MyndPlay	MyndBand BLE EEG Brainwave Headset	MyndPlay
Myneurva	At-Home Neurofeedback Program / BrainStation	Myneurva
Narbis	Narbis Neurofeedback Smart Glasses	Narbis
Neeuro	SenzeBand 2	Neeuro
Neuphony	Neuphony EEG Headband	Neuphony
Neurable	MW75 Neuro, MW75 Neuro LT	Neurable
Neuronic	Neuradiant / Neuronic LIGHT	Neuronic
NeurOptimal	NeuroOptimal® Neurofeedback System	NeurOptimal
Neurosity	Crown	Neurosity
NeuroSky	MindWave Mobile 2	NeuroSky
OpenBCI	Galea, Cyton Biosensing Board, Ganglion Board	OpenBCI
Sens.ai	Sens.ai Brain Training Headset	Sens
g.tec	Unicorn Hybrid Black Unicorn BCI Core-8	GTec
URGOTECH	URGOnight	Urgo

The table groups products and platforms by company and assigns each company a reference identifier to support later analysis

Table 4 Definitional coverage of selected neurotechnology products and platforms under reviewed legal frameworks in the EU, grouped by company

Neurotechnology Reference	*MDR*	*GPSR*	*GDPR*	*EU AI ACT*
Bía	Likely	Likely	Likely	Unclear
BrainAccess	No	Likely	Likely	Unclear
BrainBit	No	Likely	Likely	Unclear
Earable	No	Likely	Likely	Likely
Emotiv	No	Likely	Likely	Likely
Flow	Likely	Likely	Unclear	Unclear
Flowtime	Likely	Likely	Likely	Unclear
FocusCalm	No	Likely	Likely	Likely
Healium	No	Likely	Likely	Unclear
iBand	Likely	Likely	Likely	Likely
IDUN	No	Likely	Likely	Unclear
Macrotellect	No	Likely	Likely	Unclear
mBrainTrain	Likely	Likely	Likely	Unclear
Mendi	No	Likely	Likely	Unclear
Muse	No	Likely	Likely	Unclear
Myndlift	No	Likely	Likely	Unclear
MyndPlay	No	Likely	Likely	Unclear
Myneurva	No	Likely	Likely	Likely
Narbis	No	Likely	Likely	Unclear
Neeuro	No	Likely	Likely	Likely
Neuphony	No	Likely	Likely	Likely
Neurable	No	Likely	Likely	Likely
Neuronic	No	Likely	Likely	Unclear
NeurOptimal	No	Likely	Likely	Unclear
Neurosity	No	Likely	Likely	Unclear
NeuroSky	No	Likely	Likely	Likely
OpenBCI	Likely	Likely	Likely	No
Sens	Likely	Likely	Likely	Likely
GTec	Likely	Likely	Likely	Unclear
Urgo	No	Likely	Likely	Likely
Overview (companies with all marketed product/platforms covered)	8 Likely, 22 No	30 Likely	29 Likely, 1 Unclear	11 Likely, 18 Unclear, 1 No

The table considers the definitional coverage of neurotechnology companies according to legal frameworks originating in the EU [25]. Determinations were based solely on the definitional criterion of neural data, not on overall legal coverage under the listed legal frameworks. For mixed-data wearables, this means that a negative or unclear classification may reflect limited statutory coverage of all the mixed data streams or downstream inferences associated with that product, rather than the complete exclusion of the device from all regulation. Company-level grouping provides a high-level overview, as companies may apply similar practices across multiple products or platforms. However, individual neurotechnology may have distinct technical characteristics that warrant different legal or policy treatment

Devices fall under the purview of the *FDCA* whenever they are intended to be used "in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals," or to "affect the structure or any function of the body of man" [§ 321(h)(1)].[2]

If a wearable is not a medical device, it may fall under the governance of the *Health Insurance Portability and Accountability Act* (*HIPAA*) [29] when the data is transmitted to the user's physician or another *HIPAA* covered entity. All other non-medical wearables would only receive privacy protection under the Federal Trade Commission (FTC)'s unfair and deceptive practice laws, which focus on how the device is marketed and advertised, and not necessarily the actual safety of the product [30].[3] In practice, this classification turns heavily on intended use as reflected in manufacturer representations, product labelling, and marketing claims, rather than on the mere fact that a device records brain-related signals or interacts with the nervous system.

Many of the consumer neurotechnologies in our dataset are marketed primarily for wellness, focus, sleep, meditation, gaming, cognitive enhancement, or general self-monitoring, rather than for diagnosis, treatment, mitigation, or prevention of disease. On that basis, most of the products reviewed would not likely fall within current *FDCA* medical-device oversight, even where they collect neural data or generate brain-related inferences. By contrast, devices making more explicit therapeutic or clinical claims, or devices more directly framed as affecting bodily structure or function for medical purposes, are more likely to be classified as falling within the *FDCA*. Only four of the technologies reviewed would likely be considered medical devices and therefore subject to the regulation requirements under the *FDCA* (Table 5). However, we note that this landscape may change due to the recent introduction of the MIND Act of 2025.

Prospective Federal Data Protection Legislation

The MIND Act of 2025 is a congressional bill that is currently before the United States Senate. It proposes to direct the FTC to conduct a study on the governance of neurotechnology-derived data and publish the results in a report. Contained in this report will be an outline of "best practices for privacy and data security for the private sector to protect such data" [§4, (a)(1)(ii)]. The report will support executive offices develop federal guidance "regarding the procurement and operational use by federal agencies of neurotechnology that collects, uses, procures, or otherwise processes neural data or other related data" [Id. § 5 (a)(1)].

The Mind Act itself defines 'neural data' and 'other related data' broadly. The term 'neural data' includes "information obtained by measuring the activity of an individual's central or peripheral nervous system through the use of neurotechnology" [Id. § 3(1)(4)]. Neurotechnology is defined as, "a device, system, or procedure that accesses, monitors, records, analyzes, predicts, stimulates or alters the nervous system of an individual to understand, influence, restore, or anticipate the structure, activity, or function of the nervous system" [Id. § 3(1)(5)]. The term 'other related data' refers to "biometric, physiological, or behavioral information that does not directly measure the neural activity or central or peripheral nervous system of an individual, but can be processed, analyzed, or combined with other data to infer, predict, or reveal cognitive, emotional, or psychological states or neurological conditions" [Id. § 3(6)(A)]. It is noted that this may include "heart rate variability, eye tracking patterns, voice analysis, facial expression recognition, sleep patterns, or other signals derived from consumer devices, wearables, or biosensors" [Id. § 3(6)(B)].

According to these definitions, of the 30 neurotechnology devices assessed, 22 would likely fall within the Mind Act's coverage, five would not, and coverage for three devices remains unclear (Table 5). This Act is both promising and precarious. On the one hand, it could establish a degree of regulatory uniformity in the oversight of neurotechnology consumers within the US. The MIND Act would not itself establish a fully-fledged federal data protection regime, but it represents the first comprehensive federal legislative initiative addressing neural data in a systematic manner. Federal action under the MIND Act could enhance baseline expectations for neurotechnology products distributed within the American stream of commerce, even if States would retain authority to implement their own regulatory frameworks. To be

[2] It should be noted that in January 2026, the FDA issued a guidance document to outline its intention of relaxing regulations for wearables.

[3] Section (5) of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce" as defined in 15 U.S. § 45.

Table 5 Definitional coverage of selected neurotechnology products and platforms under reviewed legal frameworks in the US, grouped by company

Neurotechnology Reference	*CPA*	*CCPA*	*GIPA*	*CTDPA*	*FDCA*	Mind Act	Resolution 503
Bía	Likely	Unclear	No	Likely	No	Likely	No
BrainAccess	Likely	Unclear	No	Likely	No	Likely	No
BrainBit	Likely	Unclear	No	Likely	No	Likely	No
Earable	Likely	Unclear	No	Likely	No	Likely	No
Emotiv	Likely	Unclear	No	Likely	No	Likely	No
Flow	Unclear	Unclear	Unclear	Unclear	Likely	Unclear	Unclear
Flowtime	Likely	Unclear	No	Likely	No	Likely	No
FocusCalm	Likely	Unclear	No	Likely	No	Likely	No
Healium	No	Unclear	No	No	No	No	No
iBand	Likely	Unclear	No	Likely	No	Likely	No
IDUN	Likely	Unclear	No	Likely	No	Likely	No
Macrotellect	Likely	Unclear	No	No	No	No	No
mBrainTrain	Likely	Unclear	No	Likely	Likely	Likely	No
Mendi	No	Unclear	No	No	No	Likely	No
Muse	Likely	Unclear	No	Likely	No	Likely	No
Myndlift	Unclear	Unclear	Unclear	Unclear	No	Unclear	Unclear
MyndPlay	No	Unclear	No	No	No	No	No
Myneurva	Unclear	Unclear	Unclear	Unclear	Likely	Unclear	Unclear
Narbis	Likely	Unclear	No	Likely	No	Likely	No
Neeuro	Likely	Unclear	No	Likely	No	Likely	No
Neuphony	Likely	Unclear	No	Likely	No	Likely	No
Neurable	Likely	Unclear	No	Likely	No	Likely	No
Neuronic	No	Unclear	No	No	Likely	No	No
NeurOptimal	Likely	Unclear	Likely	Likely	No	Likely	Likely
Neurosity	Likely	Unclear	No	Likely	No	Likely	No
NeuroSky	No	Unclear	No	No	No	No	No
OpenBCI	Likely	Unclear	No	Likely	No	Likely	No
Sens	Likely	Unclear	No	Likely	No	Likely	No
GTec	Likely	Unclear	No	Likely	No	Likely	No
Urgo	Likely	Unclear	Likely	Likely	No	Likely	Likely
Overview (companies with all marketed product/platforms covered)	22 Likely, 5 No	30 Unclear	2 Likely, 3 Unclear, 25 No	21 Likely, 3 Unclear, 6 No	4 Likely, 26 No	22 Likely, 3 Unclear, 5 No	2 Likely, 3 Unclear, 25 No

The table considers the definitional coverage of neurotechnology companies according to legal frameworks originating in the US [25]. Determinations were based solely on the definitional criterion of neural data, not on overall legal coverage under the listed legal frameworks. For mixed-data wearables, this means that a negative or unclear classification may reflect limited statutory coverage of all the mixed data streams or downstream inferences associated with that product, rather than the complete exclusion of the device from all regulation. Company-level grouping provides a high-level overview, as companies may apply similar practices across multiple products or platforms. However, individual neurotechnology may have distinct technical characteristics that warrant different legal or policy treatment. *CPA* Colorado Consumer Privacy Act; *CCPA* California Consumer Privacy Act; *GIPA* Montana Genetic Information Privacy Act; *CTDPA* Connecticut Data Privacy Act

sure, this would be contingent on the FTC conducting a robust study on the subject and subsequent congressional action aligning with its findings. On the other hand, any subsequent legislation modelled on the MIND Act's approach may impose disproportionate compliance burdens on neurotechnology companies,

potentially constraining innovation or conferring a relative advantage on larger firms.

Current State-Specific Data Protection Legislation

Given the lack of comprehensive federal privacy law in the US, it has been left to individual State legislatures to enact separate privacy frameworks to address such data. At the time of writing this Article, regulations have been enhanced in Colorado (*Colorado Privacy Act*, *CPA*) [31], California (*California Consumer Protection Act*, *CCPA*) [32], Montana (*Genetic Information Privacy Act*, *GIPA*) [33], and Connecticut (*Connecticut Data Privacy Act*, *CTDPA*) [34] to encompass the data collected from neurotechnology wearables (Table 6). These regulations impose general privacy compliance obligations on private-sector businesses.

The scope and enforcement mechanisms of all four statutes vary considerably. For example, the *CPA* grants consumers an expansive set of rights, including rights to opt out of data sales, obtain data in a portable and readily usable format, and appeal decisions made by regulated entities. The *CCPA*, by contrast, only provides relatively basic rights, largely confined to access, correction, and deletion. However, these narrower protections are coupled with a comparatively stronger enforcement framework, including a private right of action and a specialized state agency tasked with overseeing compliance and enforcement. These differences merit further attention, but are beyond the scope of our current work. For present purposes, we emphasize that any comparison of statutory protections must be preceded by a clear understanding of the types of data that fall within the scope of each statute being examined.

A quick comparison of these Acts shows how coverage of neurotechnology may vary due to differences in statutory scope:

1) According to Colorado's *CPA* definition of neural data, 22 neurotechnology companies are likely to have coverage for their marketed devices, whereas the coverage for 5 remains unlikely.
2) According to California's *CCPA* definition of neural data, it is unclear (cannot be determined given the lack of information) whether there would be coverage for any of the devices being marketed by the 30 companies.
3) According to Montana's *GIPA* definition of neural data, 25 neurotechnology companies are not likely to have coverage for any of their marketed devices, 2 are likely to, and coverage for 3 remains unclear.
4) According to Connecticut's *CTDPA* definition of neural data, 21 neurotechnology companies are likely to have coverage for all of their marketed devices, 6 are unlikely to, and coverage for 3 remains unclear.

A central challenge underlying the "unclear" or "unlikely" classifications is that many consumer neurotechnologies use multimodal data streams that collect neural signals alongside physiological, behavioural, and contextual information. In such instances, statutory coverage may clearly apply to certain components of a device or program, while remaining ambiguous or inapplicable to others. Accordingly, our classifications should not be interpreted as binary determinations regarding entire technologies. Rather, they reflect the extent to which each framework appears to capture *all* of the (marketed) neural, non-neural, and inferential elements within a given mixed-data system.

Judicial interpretation will ultimately define the contours of the state-based provisions; however, an initial reading of the statutory texts reveals several ambiguities. Chief among these is the fact that the statutes make it unclear what qualifies as data "generation." All four frameworks refer to data generated through the measurement of nervous system activity, yet it remains unclear whether this terminology is intended to be interpreted narrowly or broadly. Some statutes appear to reflect a narrower conception, or perhaps a misunderstanding, of how data are produced in neurotechnological contexts. Specifically, they treat neural and non-neural data as categorically distinct, or privilege central nervous system activity. In jurisdictions where a distinction is drawn with respect to non-neural data, as in California and Montana, it is unclear whether the relevant provisions are limited to raw recordings of neural activity. This raises further questions as to whether data may lose its "neural" character once it has been processed, abstracted, or integrated with other data modalities. There almost always has to be some degree of external non-neural modality informing how to make sense of raw data, raising a further conceptual difficulty:

Table 6 Comparison of existing American State laws that directly apply to neurotechnology

Features of Comparison	Colorado HB 24-1058 Eff. Aug 7, 2024	California SB 1223 Eff. Jan 1, 2025	Montana SB 163 Eff. Oct 1, 2025	Connecticut SB 1295 Eff. Jul 1, 2025
Parent Legislation	*Colorado Consumer Privacy Act* (CPA)	*California Consumer Privacy Act* (CCPA)	*Montana Genetic Information Privacy Act* (GIPA)	*Connecticut Data Privacy Act* (CTDPA)
Scope of Application	Entities conducting business in or targeting Colorado that process personal data of ≥ 100,000 consumers per year, or process data of ≥ 25,000 consumers and derive revenue or discounts from the sale of personal data.	For-profit entities doing business in California that get a revenue ≥ $25M (inflation-adjusted), buy/sell/share data of 100,000+ consumers/households, or derive ≥ 50% revenue from selling or sharing personal information.	Non-governmental entities that offer consumer genetic testing or collect, use, or analyze genetic data of Montana residents.	Non-governmental entities (controllers or processors) conducting business in or targeting Connecticut that process data of ≥ 100,000 residents, or process data of ≥ 25,000 residents and derive ≥ 25% revenue from the sale of personal data.
These laws contain significant entity- and data-level exemptions, commonly excluding government bodies, nonprofits, higher education, and data already regulated under sector-specific laws, such as HIPPA (governs data handled by healthcare providers, insurers, and their business associates), GLBA (governs data handled by financial institutions), COPPA (governs children data), FCRA (governs data handled by consumer reporting agencies), FERPA (governs data handled by educational agencies or institutions). Applicability therefore depends heavily on both the organization type and the category of data processed.				
Definitions of Neural Data	"'Neural data' means information that is generated by the measurement of the **activity** of an individual's **central or peripheral** nervous systems and that can be processed by or with the assistance of a device. [...] 'Biological data' means [...] data is used or intended to be used, singly or in combination with other personal data, for identification purposes."	"'Neural data' means information that is generated by measuring the **activity** of a consumer's **central or peripheral** nervous system, and that is **not inferred from nonneural** information."	"'Neurotechnology data' means information that is **captured by neurotechnologies**, is generated by measuring the **activity** of an individual's **central or peripheral** nervous systems, or is data associated with neural activity, which means the activity of neurons or glial cells in the central or peripheral nervous system, and that is **not nonneural** information [...], including but not limited to pupil dilation, motor activity, and breathing rate."	"'Neural data' means any information that is generated by measuring the **activity** of an individual's **central** nervous system."
Application of Data Categories	"Neural data" is classified as a subset of "biological data," which is a type of "sensitive data." There is no explicit mention of non-neural data.	Neural data is classified as "sensitive personal information." This broader category may implicitly include non-neural data, as "biometric information," if used for identification purposes.	"Neurotechnology data" is a distinct category, alongside "genetic data" and "biological sample."	Neural data is classified as "sensitive data." There is no explicit mention of non-neural data, but such data may fit the definition of "biometric data," which is a type of "sensitive data."
Jurisdictions vary in how explicitly inferences/algorithmically derived outputs drawn from existing data categories to profile individuals are considered 'personal information.'				

Table 6 (continued)

Features of Comparison	Colorado HB 24-1058 Eff. Aug 7, 2024	California SB 1223 Eff. Jan 1, 2025	Montana SB 163 Eff. Oct 1, 2025	Connecticut SB 1295 Eff. Jul 1, 2025
Applicable Extra Protections	Heightened protections apply to "sensitive data," including mandatory opt-in consent before processing, robust data protection assessments, and continual update of privacy notices.	Heightened protections apply to "sensitive personal information," including the right to limit use and disclosure (e.g., opt-out mechanisms for sale/sharing), and enhanced notice requirements.	All regulated data is highly sensitive, rendering a tiered classification system unnecessary. If the definition above does not apply, data handling would be governed by Montana Unfair Trade Practices and Consumer Protection Act.	Heightened protections apply to "sensitive data," including mandatory opt-in consent required before processing or selling, purpose limitations, and robust data protection assessments (for each controller processing activity).
These protections are in addition to any general consumer rights applicable to all categories of personal data.				
Treatment of Mixed-signal Data Wearables	Likely covered, as both neural and physiological data are protected biological data.	Possibly covered, if non-neural data qualifies as biometric information.	Unlikely to be covered, as non-neural data falls outside the Act's scope.	Likely covered, as non-neural data seems to fit the definition of biometric or health information.
Overall Statutory Coverage	Definitions imply **strong coverage** of selected devices under the current framework (29 companies yes, 1 unclear).	Definitions imply **ambiguous coverage** of selected devices under the current framework (30 companies unclear).	Definitions imply **weak coverage** of selected devices under the current framework (5 companies yes, 1 unclear, 24 no).	Definitions imply **strong coverage** of selected devices under the current framework (29 companies yes, 1 unclear).

The table compares four US data protection legal frameworks based on their parent legislation, scope of application, definitions of neural data, treatment of data categories more broadly, additional protections applicable to certain data categories, and treatment of mixed-signal wearable data, providing an overview of the extent of statutory coverage. Mixed-signal wearables are those handling both neural and non-neural data. *HIPAA* Health Insurance Portability and Accountability Act; *GLBA* Gramm-Leach-Bliley Act; *FCRA* Fair Credit Reporting Act; *DPPA* Driver's Privacy Protection Act; *B2B* business-to-business

where, precisely, should the line between neural and non-neural data be drawn when both are being used in the same technology?

This difficulty becomes clearer through illustrative cases. Heart-rate variability collected for cardiovascular or fitness monitoring is not functionally equivalent to heart-rate variability collected alongside EEG and breathing data to infer anxiety, stress, or attentional state during an evaluative interaction. Likewise, app engagement data or cognitive test scores may appear relatively mundane in isolation, yet take on a different meaning when combined with neural signals to generate profiles of cognitive strain, focus, or neurofeedback progress. Even contextual data, such as head movement or body motion, may become integral to interpreting neural recordings when used to classify fatigue, engagement, or sleep-related states.

In each case, the governance concern does not arise from the non-neural signal in the abstract, but from its role within a mixed-data inferential system. A regulatory framework that protects the neural component while treating accompanying physiological, behavioural, or contextual streams as categorically separate risks missing the operation of the system as a whole. It may also encourage undesirable outcomes. For instance, requiring strict separation of neural from non-neural data can introduce both practical and cybersecurity vulnerabilities. In many systems, these data streams are stored in unified databases or integrated file formats; separating them may require custom pipelines, duplicated storage, and significant re-architecting. This not only increases system complexity and the overall attack surface, but can also compromise data integrity, particularly if re-alignment across fragmented datasets becomes necessary [35].

Even if systems combining neural and non-neural inputs could, in practice, attract the additional protections associated with the presence of neural data, the structure of the regime raises deeper questions about its normative coherence. Where non-neural signals perform the majority of inferential or predictive work within a system, it is not self-evident why regulatory priority should attach primarily to the neural component rather than to the functional outputs or dominant data modality. The resulting framework risks privileging a formalistic distinction over an analysis of substantive difference, thereby calling into question the underlying justificatory basis for differential treatment across data types. It is not inconceivable that non-neural, neurotechnology-related data alone may sometimes be just as revealing as neural data upon aggregation with other non-neural data forms.

Consider Flow Neuroscience, a consumer neurotechnology product that delivers transcranial direct current stimulation for the treatment of depression. While the device does not itself collect neural recordings, it nevertheless generates closely related forms of personal data. Its companion application helps users configure stimulation protocols and includes a chatbot through which they can discuss symptoms, while also storing self-reported mental health information. In clinical contexts, a clinician-facing version of the app may additionally provide real-time information on patient adherence and treatment outcomes. The mere fact that an individual is using Flow for depression treatment—and whether that treatment appears effective—produces highly informative behavioural signals. If inadequately protected, such data could be commercially exploited and combined with other datasets to infer or predict sensitive patterns of behaviour, revealing insights about mental health that extend well beyond the device's immediate technical scope.

Another question that none of these frameworks seem to address is how we should think of data *about* neural data. Where neural signals are used exclusively as training inputs for machine learning systems, and no raw neural recordings persist within the deployed model, it is ambiguous whether the resulting model parameters or outputs fall within regulated categories. This uncertainty extends further to the question of whether model weights shaped by neural datasets may themselves be characterised as 'neural data,' as well as whether downstream synthetic outputs (e.g., focus scores, calm indexes, sleep stages, stress levels) generated by such systems should be treated as falling within the scope of regulation. In such scenarios, no new "measurement" of neural activity would occur at the point of inference, but rather previously collected and subsequently de-identified data is repurposed in predictive modelling. In such cases, ostensibly non-neural signals may be statistically associated with particular neural states, thereby enabling inference about brain activity without direct measurement.

It is possible that the gaps left behind by these frameworks could incentivise suboptimal data governance practices. If the inclusion of neural inputs triggers additional compliance obligations, regulated entities may

rationally respond by reducing reliance on neural signals while simultaneously expanding the collection and granularity of alternative behavioural or physiological data in order to preserve predictive performance. As a result, we would see an increase, rather than constraining, of overall behavioural surveillance. Alternatively, such regulatory asymmetries may give rise to regulatory arbitrage [36], as firms relocate operations to jurisdictions with less stringent oversight, thereby contributing to a broader "race to the bottom" in regulatory standards.

Positions of Professional Associations

Numerous American associations advocate for responsible neuroscience research and development (e.g., the American Academy of Neurology, the Neurorights Foundation, the Society for Neuroscience), yet relatively few have issued formal position statements specifically addressing consumer neurotechnology. The American Medical Association (AMA) is among the first to do so. It recently adopted Resolution 503, "Safeguarding Neural Data Collected by Neurotechnologies," contributing to a broader set of emerging legislative and regulatory efforts aimed at strengthening oversight of commercial neurotechnologies. Given the AMA's institutional size and authority, this resolution may play an influential role in shaping future approaches to neural data governance.

Resolution 503 defines 'neural data' as "information obtained by measuring the activity of a person's central or peripheral nervous system through the use of neurotechnologies," and explicitly states that it "does *not* include inferential data from non-neural information" [emphasis added]. As discussed above, many companies routinely collect and integrate signals such as eye movements, cardiac activity, derived cognitive performance metrics, and application usage data to generate predictions or conduct research. This raises important questions about how the AMA envisions regulating consumer neurotechnologies that rely on combined neural and non-neural data streams. The definitional approach adopted in Resolution 503 thus closely mirrors that seen in Montana's *GIPA*. As a result, it similarly suggests that 25 of the neurotechnologies examined would fall outside full coverage under this narrow framing, 2 would likely be covered, and 3 remain unclear (Table 5).

The fact that a leading medical authority has adopted this distinction is not without rationale; it likely reflects an effort to preserve conceptual precision around what counts as a direct measure of nervous system activity and avoid overextending medical terms like 'neural data' into domains where clinical consensus is less settled. Nevertheless, because such statements often function as reference points for policymakers and industry alike, there is a risk that they may inadvertently reinforce the tendency to treat neural and non-neural data as distinct regulatory categories. The implications of this remain uncertain, but we raise it as a possibility.

Relevant Overlapping Legal Frameworks

A federal priority that could further present a challenge for neurotechnology-related data protection is the push for rapid AI development. The EO 14179, "Removing Barriers to American Leadership in Artificial Intelligence," aims for extreme deregulation of emerging technology [37]. The purpose of the EO is to achieve AI global dominance. It is based on three pillars: (1) Accelerate AI Innovation, (2) Build AI American Infrastructure, and (3) Lead in International Diplomacy and Security. The EO specifically values increasing the use of open-source and open-weight AI systems, streamlining the approval process of building data centers, and rapidly exporting and distributing American AI technology, among many other mechanisms. The EO states: "The United States must lead the creation of the world's largest and highest quality AI-ready scientific datasets, while maintaining respect for individual rights and ensuring civil liberties, privacy, and confidentiality protections" [37].

The EO is devoid of specific recommendations on how to accomplish its aspirations. It directs the National Science and Technology Council (NSTC) Machine Learning and AI Subcommittee to make "recommendations on minimum data quality standards for the use of biological, materials science, chemical, physical, and other scientific data modalities in AI model training," [37] and provides for the bolstering of cybersecurity infrastructure. However, it only does so for the use of national security applications. It does not classify AI systems and the risk they may impose on individual rights. Moreover, in December 2025, the White House issued another EO titled "Ensuring a National Policy Framework for Artificial Intelligence" [38]. The EO aims to expedite instituting minimal federal regulation of AI. This

EO established an AI Litigation Task Force to review State-level AI regulatory frameworks and assess whether they are unduly burdensome or overreaching. At the time of writing, this review would have encompassed 38 State laws.

It is worth noting here that the AI-related EOs and MIND Act have competing goals. There is a rapidly expanding number of neurotechnology devices that utilize AI to decode neural activity, adaptively personalize stimulation, predict user behavior, and interpret cognitive or emotional states [39, 40]. Because of this, the EOs could accelerate product development while simultaneously weakening safeguards for sensitive neural data. If these EOs are implemented without adequate guardrails, regulatory inequities may emerge. Neurotechnologies that do not incorporate AI could remain subject to stricter existing regulations, while more advanced AI-enabled neurotechnologies avoid equivalent scrutiny. This would be paradoxical, given that both types of devices could rely on similar categories of neural data and may generate inferences that carry significant risks of harm. Companies could therefore be incentivized to incorporate AI simply to benefit from deregulation. In turn, federal policy would continue to focus on which technologies merit (de)regulation, rather than addressing how the collection, use, and disclosure of data meaningfully affect the well-being of individuals or groups. This tension mirrors long-standing debates in the regulatory literature over the merits of technological neutrality [41, 42].

Current State of Protection for Neurotechnology in the European Union

Current Product Regulation

Returning now to product regulation—this time, in the European context—we note the *MDR* operates with greater specificity than the *FDCA*. The *MDR* applies to non-medical, non-invasive brain stimulation devices produced by commercial developers or sponsors of clinical research. Its scope begins before a device is developed and continues after it has entered the market. Unlike data protection laws, its emphasis is less on how consumer data is *used*, and more so on how devices *operate* to achieve their intended purpose. Over three years ago, the European Commission (hereinafter "the Commission") revised the *MDR* through the implementation of Annex XVI,[4] which categorizes select products intended for non-medical use as Class III devices.[5] Pursuant to Annex XVI, non-invasive consumer brain-computer interfaces (BCIs) lacking a medical purpose are classified as Class III devices and are defined as: "Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields penetrating the cranium to alter neuronal activity in the brain." As a result, non-invasive neurostimulating devices BCIs are now subject to the most stringent level of regulatory oversight. Meanwhile, non-invasive BCIs that record brain activity without stimulating it, are not subject to Class III requirements. The highest classification they could receive is Class IIa, provided they have a medical purpose [43].

The research community has widely criticized this amendment, arguing that strict classification will hinder research and innovation [43]. They contend that the evidence used to reclassify non-invasive consumer BCIs "grossly misrepresents the risks of these devices;" the amendment relied on just five peer-reviewed journal articles, despite the Commission having access to numerous peer-reviewed studies concerning atypical brain development related to BCIs. The community also notes that these five papers may have documented only rare cases of

[4] Annex XVI lists products without an intended medical purpose referred to in article 1(2), including contact lenses, surgically invasive body modification devices, dermal fillers (excluding tattoos), adipose-reduction equipment, high-intensity light/laser devices for skin, and equipment for brain stimulation using electrical or magnetic fields.

[5] **Class I** refers to low-risk, non-invasive devices. Manufacturers must issue an EU declaration of conformity and prepare technical documentation. Sterile devices, measuring devices, and reusable surgical instruments require additional certification by a EU notified body according to Annex IX or Annex XI (otherwise, self-declaration). **Class IIa** refers to low–medium risk, short-term implants ($\leq$30 days). Manufacturers must provide an EU declaration of conformity, technical documentation (device description, risk management, labeling, clinical evaluation), and undergo a conformity assessment by a EU notified body per Annex IX/X and XI. **Class IIb** refers to medium–high risk, longer-term implants (>30 days). Same requirements as IIa, with more strict review for certain pathways. **Class III** refers to high-risk devices, often long-term or implantable. Manufacturers must provide all the documentation and evidence required for the lower classes, but the review process by the EU Notified Body is more comprehensive, and post-market requirements are stricter.

abnormal brain activity, potentially leading to inaccurate assessments of actual risk thresholds. Furthermore, there is ambiguity in the *MDR* regarding Research Use Only (RUO) devices. Consequently, the research community has been seeking clarification on whether RUO devices now fall under class III requirements [43]. Such a change is seen to hinder academics conducting basic research and, as a result, companies that use basic research studies as benchmarks when developing, evaluating, and monitoring their products. At present, 8 of the 30 neurotechnology companies would likely have their devices subject to the highest *MDR* regulations based on the new definition of BCIs referenced above (i.e., that the *MDR* only covers devices that stimulate the nervous system) (Table 4).

Non-invasive and non-medical consumer neurotechnology wearables that do not fall under the scope of the *MDR* must refer to the *GPSR* to identify any applicable regulations. The *GPSR* establishes comprehensive safety requirements for products and was recently revised to address issues specific to digital products. Article 6 of the *GPSR* outlines the necessary features for product safety assessments, including characteristics of the product, interactions with other products, presentation, consumer-specific considerations, appearance, cybersecurity measures, and predictive functionalities. Recital 23 emphasizes that "safety assessments," should consider "health risks associated with digitally connected products, including mental health risks to vulnerable consumers, and evaluate product safety throughout its entire lifecycle." To be clear, these provisions do not explicitly reference particular products or technologies. Moreover, while the *GPSR* includes provisions on cybersecurity and data privacy, its primary focus remains product safety. Consequently, data protection risks related to consumer neurotechnology may be more thoroughly addressed within the framework of the GDPR, even though the *GPSR* is likely to apply (to some extent) to all reviewed products and platforms (Table 4).

Data Protection Regulation

The *GDPR* constitutes a comprehensive legal framework that regulates the collection, processing, and storage of personal data for individuals within the EU. This Regulation acknowledges individual privacy as a fundamental right, which stands in stark contrast to most US privacy frameworks that are centered around protecting consumers from unfair and deceptive data practices within the marketplace. In the *GDPR*, data subjects have the right to be informed, the right of access, the right to rectification, the right to erasure, the right to restrict processing, the right to data portability, right to object, as well as rights related to automated decision-making and profiling. While the *GDPR* does not specifically reference 'neural data,' there are three broad categories within its framework under which it could be classified: (1) 'personal' under Article 4(1); (2) 'biometric,' under Article 9(1); and/or (3) 'health' under Article 9(1) [44],[6] regardless of whether 'non-neural data' is collected. This rights-based framework is likely broad enough to cover the neurotechnologies being developed by 29 of the 30 companies reviewed, with only 1 remaining unclear (Table 4). That said, the extent to which inferences are covered under the *GDPR* is still an open question [45]. The *EU AI Act* becomes a key instrument in this regard.

Relevant Overlapping Legal Frameworks

For neurotechnology devices that use AI, consumer data protections can be governed by the *EU AI Act*, which is complementary to the *GDPR* by incorporating a risk-based approach. Through this approach, the *EU AI Act* creates a model of tiered regulation that could influence how policymakers think about the governance of neural data privacy. Whereas emerging neural data protection initiatives and digital rights charters primarily focus on safeguarding data ownership and privacy, the *EU AI Act* takes an impact-oriented approach [46]. It does not regulate how AI systems are built or what data they rely on, but rather how their deployment affects individuals

[6] The provisions define personal data broadly as any information that can directly or indirectly identify an individual. Even when data does not uniquely identify a person, they may still fall under special categories of data if they reveal sensitive attributes, (e.g., political opinions or ethnic origin) or qualify as biometric data. Neural data could be considered biometric data, given that it involves "specific technical processing relating to the physical, physiological or behavioral characteristics of a natural person." Alternatively, it could be viewed as health data, since it reveals information about an individual's "current or future physical or mental health" through "the testing or examination of a body part or bodily substance." The GDPR's definition of health data does not require the data source to be a medical device, potentially covering data generated by non-medical consumer wearables when processed for health-related purposes.

and society. This shift from data ontology to societal impact may be the move that neurotechnology governance requires, particularly where brain-derived data may influence cognition, behaviour, and personal autonomy in ways that extend beyond privacy concerns.

Annex III of the Act provides detailed criteria for identifying high-risk systems; however, considerable uncertainty remains regarding the classification of many non-invasive consumer neurotechnology wearables. As scholars have increasingly observed, broadly framed and potentially indeterminate concepts of "risk," combined with the EU's co-regulatory approach, may contribute to inconsistent regulatory interpretations [47]. Nonetheless, we propose a preliminary framework for mapping consumer neurotechnology applications onto the *EU AI Act*'s four-tier risk classification system (Table 7). This initial exercise suggests that neurotechnology applications may span the full spectrum of regulatory implications envisioned by the Act, ranging from the prohibition of covert neural manipulation (unacceptable risk) to minimal regulatory oversight for entertainment-oriented EEG devices (minimal risk).

Applying the *EU AI Act* to neurotechnology could be done by considering both (i) the purposes for which they collect and process neural data, and (ii) the complexity of the algorithms applied to such data. The comprehensive list of high-risk AI systems referenced in Article 6(2) of the *EU AI Act* is set out in Annex III,[7] with Sect. 1(c) designating AI systems used for emotion recognition as high-risk. Because many consumer neurotechnology wearables employ signal-processing algorithms to infer users' emotional states, such systems could reasonably be classified as high-risk emotion recognition technologies, even in the absence of AI functionalities. Alternatively, neurotechnology wearables may be deemed high-risk under Article 7(2)(c) of the *EU AI Act*, which directs regulators to consider "the nature and amount of data processed and used by the AI system, in particular whether special categories of personal data are processed." Non-invasive neurotechnology wearables may meet this threshold, as consumer neurotechnology firms often process disproportionately large volumes of neural data. Neurotechnology companies generally require only about 1/100th of the original brain scan size or 1/10,000th of the initial amount of information collected [21]. As a result, they often extract substantially more data than is necessary.

If we assume that the Act applies only to devices that explicitly identify the use of AI in their software systems, 11 of the 30 reviewed neurotechnology companies would likely have their devices covered, 18 are unclear, and 1 would not (Table 4). However, it remains possible that the scope of the Act could be interpreted more broadly. The EU Act defines an AI system as "a *machine-based system* that is designed to operate with *varying levels of autonomy* and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, *infers, from the input it receives, how to generate outputs* such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" [emphasis added]. Recital 12 further clarifies that "varying levels of autonomy" refers to systems possessing "*some degree* of independence of actions from human involvement and of capabilities to operate without human intervention" [emphasis added]. This broad formulation leaves open the possibility that the Act could apply beyond systems explicitly marketed as AI-driven, depending on how the concept of AI is interpreted in practice.

This ambiguity connects to a broader debate within AI regulation and scholarship about whether "AI" denotes a defined and technically distinct class of systems, or functions primarily as a socially or commercially constructed label. Commentators have argued that "AI" is often invoked as an umbrella term encompassing a heterogenous collection of computational techniques that in practice obscures important differences in how systems operate and are deployed [48, 49]. From this perspective, the breadth of the *EU AI Act*'s definition may be viewed as a response to the difficulty of drawing clear, technical boundaries around AI itself. This breadth further underscores the extent to which neurotechnology and AI may be framed either as interrelated domains or as

[7] AI systems are high-risk if they are listed as biometrics and their use is permitted under relevant Union or national law. These systems include: "(a) Remote biometric identification systems. This shall not include AI systems intended to be used for biometric verification the sole purpose of which is to confirm that a specific natural person is the person he or she claims to be; (b) AI systems intended to be used for biometric categorisation, according to sensitive or protected attributes or characteristics based on the inference of those attributes or characteristics;

(c) AI systems intended to be used for emotion recognition."

Table 7 Illustrative mapping of consumer neurotechnology onto the *EU AI Act* risk categories

Risk category	Description in the *EU AI Act*	Consumer neurotechnology illustrative mapping	Regulatory implications
Unacceptable Risk	Poses a clear threat to safety, fundamental rights, or democracy; prohibited.	Consumer neurotechnologies that manipulate cognition, behaviour, or decision-making without informed awareness or meaningful consent. This may include closed-loop neurostimulation or neurofeedback systems, as well as brain-monitoring technologies used for social scoring, political influence, or other forms of behavioural manipulation and surveillance.	Total ban; such technologies cannot be marketed or deployed.
High Risk	Significantly impacts health, safety, or fundamental rights, especially in medical, workplace, or educational settings.	Consumer neurotechnologies that generate, infer, or act upon information about an individual's mental state in ways that may significantly affect health, safety, fundamental rights, or life opportunities. This may include devices used for medical purposes, regardless of how they are marketed, as well as wearable systems deployed in consequential settings such as employment, education, or insurance.	Must comply with strict requirements: risk management, high-quality datasets, transparency, human oversight, post-market monitoring.
Limited Risk	Lower potential for harm, but requires transparency obligations.	Consumer neurotechnologies used for wellness or self-monitoring purposes that process neural data while affording users a greater degree of control over data handling. This may include virtual reality headsets with integrated neurofeedback and emotion-recognition applications linked to wearable sensors.	Users must be clearly informed if AI is being used and how their neural data is processed; opt-out must be possible.
Minimal or No Risk	Trivial or benign applications with negligible risk.	Consumer neurotechnologies that are unlikely to generate sensitive inferences without substantial aggregation with other data sources. This may include entertainment-oriented neurotechnologies (e.g., gaming EEG headsets) and non-invasive wellness applications that process data locally and do not store neural data in the cloud.	No additional regulatory obligations under the AI Act.

The table presents a preliminary and illustrative mapping of how the *EU AI Act* risk categories may apply to consumer neurotechnology. It does not suggest that these distinctions are clear-cut in practice, nor that regulatory boundaries should be interpreted as strictly separable in this manner

analytically distinct fields, depending on how the boundaries of "AI" are drawn. Some scholars have introduced the term neuro-AI to describe systems that integrate both domains [50]. Regardless, even neurotechnologies that do not employ AI in a narrow technical sense, but do use some form of classical algorithmic calculations, could arguably satisfy the statutory thresholds of autonomy and inference set out in the *EU AI Act*. Many consumer neurotechnologies rely on complex, largely automated data-processing mechanisms that infer users' mental states, adjust to new inputs, and generate outputs without direct human oversight. Using this approach, all 30 neurotechnology companies we examined would fall within the *EU AI Act*'s regulatory ambit, provided the systems also get captured by one of the risk categories. The next question that would need to be explored is, *should* they?

Discussion

Our analysis suggests that, relative to Europe, the US neural data frameworks are more strongly organized around how data is collected, rather than the insights data produce. It is possible that the "Brussels Effect" could lead US-based organizations to adopt EU rules as de facto global standards without formal legal harmonization [51]. However, it is unlikely that all firms can absorb the associated costs, or will do so in the near term [52]. Those that do not may instead default to the regulatory frameworks of their respective State jurisdictions. In States that have already enacted specific provisions relating to neural data, achieving harmonisation with EU standards may be challenging; the laws are still new and there may be insufficient evidence to justify amendment. This is not inherently problematic, but adds some complexity. Efforts aimed at cooperative harmonisation are sometimes regarded as less effective than more unilateral forms of legal transplantation [53]. We therefore suggest that our analysis is best understood as identifying key lessons for jurisdictions that have yet to develop comprehensive frameworks governing neural data. Such lessons arise at multiple stages of the regulatory process, including the determination of the applicable legal regime, definitional inconsistencies within those regimes, and the influence of governance mechanisms beyond formal law.

The Determination of the Applicable Legal Regime

First, salient lessons emerge from the extant fragmentation of classification regimes, particularly with respect to the uneven triggering of product safety and data protection frameworks across neurotechnologies. In the US, neurotechnology product safety is governed by the *FDCA* and is subject to FDA oversight only if intended to be used in medical ways. Devices that fall outside this definition are immune from product safety regulations. By contrast, the EU adopts a comparatively more expansive approach. Under the *MDR*, certain non-invasive consumer neurotechnologies may be brought within scope, including brain computer interfaces that actively stimulate neural activity. Where devices are limited to the recording of neural activity, they may fall outside the *MDR* but remain subject to the *GPSR*, which imposes baseline safety obligations of general application. Although these instruments are not neurotechnology-specific, they nonetheless provide a more comprehensive baseline of product safety oversight than their US counterpart.

This comparative divergence suggests that a plausible regulatory approach to product safety may lie in the imposition of universal baseline protections across all neurotechnology products (or functionally analogous devices), irrespective of medical designation, supplemented by graduated tiers of regulatory intensity calibrated to both intended use and risk classification. Of course, the efficacy of such an approach would be contingent upon the accuracy of the underlying classification exercise. As the EU's *MDR* demonstrates, the up-classification of non-invasive neurostimulation devices illustrates how overly broad categorization and misjudged risk assessments can have significant implications for research and innovation, particularly where scientific and practitioner consultation is limited or inadequate [18, 43]. Nonetheless, such an approach may constitute a more coherent starting point for jurisdictions seeking to regulate neurotechnology at the product level.

Data protection is arguably equally disjointed. In the US, data protection regulation consists of a complex array of federal- and State-level statutes. *HIPAA* currently serves as the primary federal framework under which neural data may be covered, but only when collection occurs through a *HIPAA*-covered entity. The FTC's laws regarding unfair and deceptive practices also provide limited proactive safeguards,

allowing for civil liability, should a company fail to employ best practices in the event of a data breach. Connecticut, Colorado, California, and Montana, have enacted neural data privacy legislation, each with its own definition of nervous system activity and distinct consumer rights depending on the jurisdiction. In the EU, neither the *EU AI Act* nor the *GDPR* provides a specific definition for neural data. However, if neural data falls under the categories covered by these regulations, comprehensive data protections would apply to neurotechnology devices.

In light of these divergences, it may be desirable for US state-level legislation to articulate more explicit provisions concerning neural data, clarifying the circumstances under which *HIPAA*-style sectoral governance is intended to displace reliance on FTC unfair-and-deceptive-practices enforcement. Such determinations could be grounded in a more functional assessment of the nature and sensitivity of information ultimately disclosed about an individual, as well as the purposes for which such information is processed and deployed. Where a HIPAA-style framework is deemed more appropriate, its application should be expressly articulated in operational terms, including the scope of covered conduct and attendant obligations, rather than being left to rest on a cursory definitional reference to 'neural data' alone. This approach may help address regulatory gaps that arise where neural data generated outside traditional *HIPAA*-covered contexts would benefit from the extra provisions offered by sectoral health privacy protections.

These reforms should be understood with the important caveat that, while they would meaningfully improve coherence, they do not fully resolve the normative and operational overlap that can arise when product safety and data protection regimes are engaged simultaneously but reflect divergent regulatory logics. For example, a neurotechnology device presenting minimal physical or physiological risk may nevertheless infer highly sensitive affective or emotional states from neural signals, whereas a comparatively riskier device in terms of physical safety may engage in no meaningful data extraction. Absent greater institutional coordination between these regimes, such asymmetries may generate regulatory uncertainty for data handlers, potentially distorting compliance incentives [54].

Definitional Inconsistencies within Legal Regimes

Another lesson pertains to fragmented definitional approaches seen across jurisdictions. This inconsistency is particularly stark when comparing the levels of protection offered across the US States of Montana, Connecticut, California and Colorado. Laws in these States focus on neurotechnology devices that directly measure signals from the nervous system, regulating data captured from the brain, but little beyond that. In effect, protection attaches only at the input stage of the data channel. A company that uses raw EEG signals to infer an anxiety pattern would be regulated because the data originates in neural activity. By contrast, a device that infers the same anxiety pattern from a non-neural source, such as typing behavior, would not always be. The result is the same, but the level of protection differs solely because the input source is different. Similarly, if a company converts EEG signals into an inferred profile and then deletes the raw data, that inference would likely fall outside the law's protection. The same uncertainty arises when signals originate in the nervous system but are measured later in muscle or cardiovascular tissue. Although the sensor is placed on non-neural tissue, the data may still reflect neural activity or its downstream effects, making the boundary of protection unclear.

At the core of these difficulties lies a conceptual disagreement about which kinds of data should qualify as 'neural data.' Our comparison does not even account for the many States whose statutes make no explicit reference to such data at all. If these other States were to be included in the analysis, they would likely reveal an even more fractured governance landscape. We thus worry that US legal frameworks taking such compartmentalized approaches—treating 'neural data' as categorically distinct from 'non-neural data'—are generally unhelpful as a matter of data governance and consumer protection. They appear to distract from a more pressing regulatory concern: how best to govern the downstream *impacts* of neurotechnology.

This brings us to why the inclusion of inferential data should be a consideration for neurotechnology governance. Our analysis of the US clearly shows how raw EEG data may often be protected at the point of collection, but slowly become uncertain as those data

move through processing pipelines and are combined with other physiological, behavioural, or contextual signals. The product-level analysis suggests that governance frameworks should account not only for the origin of the signal, but also for the computational and access conditions under which data are processed. Several consumer neurotechnology products combine neural signals with other data streams, while also relying on algorithmic processing, real-time feedback, or developer-facing interfaces. These features matter because sensitive inferences may emerge downstream from the original measurement event, particularly when mixed data are transformed into classifications of focus, stress, sleep, fatigue, emotional state, or neurofeedback progress. Open developer access through software development kits (SDKs), application programming interfaces (APIs), or related tools may further expand the governance problem by enabling third-party recombination or repurposing of data beyond the manufacturer-controlled environment.

The Bía Sleep Smart Mask illustrates this problem. The device uses EEG to measure brain activity during sleep and combines this with biosignals and eye-movement data to infer sleep stages. This creates multiple sources of information that must be analysed to determine what, if any, US laws apply. In Colorado, accessible raw EEG data would likely be covered, while biosignals would be covered only if used for identification. If sleep-stage outputs could be used to identify an individual, those outputs and related inferences may also fall within protection. In California, raw neural data is protected at collection, and heightened protections may apply when neural data are used to infer a characteristic. However, if the same inference is drawn from non-neural information, protection becomes less certain. The key question is therefore whether the sleep-stage output is treated as derived from 'neural' or 'non-neural' information. Montana provides narrower protection: accessible raw neural signals may be covered, but biosignals and downstream inferences would likely fall outside the statute where they are treated as non-neural information. Connecticut is also uncertain because its definition is limited to central nervous system data. EEG brain activity would likely be covered, but eye-movement data may fall outside the neural-data definition, unless it qualifies separately as biometric or health-related sensitive data. In each case, protection depends less on the sensitivity of the resulting inference than on how the relevant data source is classified.

This example demonstrates why relying exclusively on the source of collection may be inadequate for rapidly evolving consumer neurotechnology. A sleep-stage classification, stress profile, focus score, or fatigue estimate may carry similar privacy and autonomy implications regardless of whether it is generated from EEG alone, from non-neural biosignals, or from a mixed-data pipeline.

The EU approach may be preferable in this respect. The frameworks in this jurisdiction do not explicitly define "neural data," yet they establish mechanisms through which such data may nonetheless be brought within existing protective regimes. Neural data, for example, could potentially be classified as a "special category of data" under Article 9 of the *GDPR*, or neurotechnologies may fall within the scope of Article 6(2) of the *EU AI Act*, as high-risk emotion recognition technologies, as well as under Article 7(2)(c), which addresses the volume of data processed. Once brought within these frameworks, effective governance need not rely on precise technological definitions or an exhaustive focus on the technical characteristics of emerging systems, but can instead be oriented toward assessing their impacts. Echoing longstanding debates in technology law, regulatory design should operate in this way because it prioritizes preserving the law's capacity to protect the underlying societal interests it was enacted to safeguard [55]. Namely, interests like privacy, autonomy, dignity, and protection from cognitive or behavioral manipulation. While we acknowledge that this model may imperfectly secure substantive rights protection in practice [56], it certainly offers a degree of regulatory flexibility currently lacking in the US. The MIND Act moves in the right direction, but remains several years away from implementation, and may ultimately conflict with deregulatory federal policy trends aimed at encouraging innovation.

Governance Mechanisms Beyond Formal Law

A final lesson emerging from our analysis concerns the role of professional oversight bodies and executive instruments. The key challenge is not whether these forms of soft law should exist, but how they interact with formal legal frameworks. While they can serve as valuable interpretive resources, they may also introduce complexity for lawmakers attempting to draft

neurotechnology-related regulatory frameworks. Greater engagement with such governance instruments, alongside clearer articulation of where and why lawmakers align with or depart from them, would help improve regulatory coherence. In their absence, policymakers and industry actors responsible for determining institutional neural data governance practices are left to determine which non-binding instruments warrant greater weight, increasing the risk of inconsistent interpretation and poorly prioritized compliance choices.

This risk may be particularly pronounced in the current US governance landscape. The AMA's Resolution 503, while not legally binding, reflects an approach to neural data governance that currently diverges from the MIND Act's broader regulatory scope. The MIND Act, in turn, diverges from relevant EOs. With the status quo being that AI governance is primarily driven by the executive branch, it opens reasonable questions as to whether soft law mechanisms are still useful in today's governing climate given the stark changes in approaching AI regulation that constantly changes with every new administration. In the EU context, there is no direct analogue to the AMA, aside from the Standing Committee of European Doctors, which has yet to issue a resolution on neural data privacy. Internationally developed governance instruments may serve as the closest equivalent source of professional or ethical guidance available to Member States. One recent example is the United Nations Educational, Scientific and Cultural Organization (UNESCO)'s "Recommendation on the Ethics of Neurotechnology," which underwent years of development and consultation and came into force in late 2025 [57].

Whether external governance instruments are ultimately beneficial or detrimental remains an open question. Soft-law mechanisms are only as durable as the political and institutional commitments that support them [58]. Nonetheless, given the pace of neurotechnology innovation, such strategies are likely to remain an important feature of governance. The task, therefore, is not to abandon soft law, but to develop clearer principles for when and how it should be used. In jurisdictions without dedicated neural data legislation, governments may benefit from first actively engaging with existing soft-law instruments to establish tentative expectations. This may then be followed by the introduction of more targeted incentives, such as procurement preferences, liability safe harbours, or certification schemes [55, 59], to encourage institutional uptake of such instruments. Where these measures prove insufficient, lawmakers could move toward the development of binding legal frameworks. Such an incremental approach may encourage early capacity-building by consumer neurotechnology companies without prematurely imposing rigid mandates that could stifle innovation. This could ensure preparedness for eventual hard-law regulation.

Conclusion

We began this research by showing how divergent uses of the term 'neural data' fracture consumer protection in neurotechnology governance. Across disciplines, competing interpretations produce substantially different conceptions of what 'neural data' entails, making a single, uniform definition difficult to achieve in policymaking. Despite increasing neuroethical attention to neurotechnology-derived data, our comparative analysis demonstrates that fragmented regulatory and policy approaches (within the US, and between the US and Europe) create a governance landscape that is difficult to translate into effective consumer protection in practice. We therefore argue that what is ultimately at stake in the protection of 'neural,' 'neurological,' or 'brain' data is not the raw physiological signal itself, but the inferences drawn from it about individuals' internal mental states, the behavioral predictions these inferences enable, and their downstream consequences. This interpretive dimension emerges precisely because mental states are not directly accessible without algorithmic mediation, and even where human oversight exists, it frequently operates through algorithmic outputs as decision-support rather than direct interpretation of neural signals.

While emerging hard and soft law mechanisms developed for AI may eventually provide a sufficient regulatory foundation for addressing consumer neurotechnology, this will likely depend on their explicit grounding in human rights principles. In the interim, jurisdictions in the US that have not yet enacted neural data-specific legislation should reconsider whether targeted neurotechnology regulatory frameworks are necessary, or whether existing regimes can be adapted to include clearer pathways for product safety, data protection, and the governance of inferential data, alongside a more deliberate articulation of how soft and hard law instruments should interact. Of course, this would need to be approached carefully. Given the breadth of existing legal frameworks already applicable to non-invasive

consumer neurotechnologies, the proliferation of overlapping regulatory schemes may heighten the risk of fragmentation and regulatory failure. Until governments develop a coordinated strategy that ensures both internal and external efficiency, incremental amendments to existing legislation that nominally account for 'neural data' may risk producing the appearance of progress without delivering substantive protection.

Emerging regulatory models for high-risk algorithmic systems, particularly in jurisdictions such as the EU, indicate that many of the privacy and accountability challenges associated with neurotechnology may be more effectively addressed within broader technology governance frameworks, rather than through siloed legal categories centered exclusively on 'neural data.' Technological innovation and robust protection of individual rights are not mutually exclusive, but they do require regulatory clarity, coordination, and conceptual precision. We therefore encourage future dialogue to move beyond high-level ethical abstraction and instead engage directly with the terminological challenges that will determine whether 'neurotechnology governance' can function effectively in practice.

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Declarations

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