Proposal for Australian Neurocognitive Rights and Advanced Neurotechnology Act

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JUSTIFICATION FOR THE AUSTRALIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

NECESSITY AND URGENCY

Australia stands at a critical technological inflection point that demands immediate legislative action. The Australian Neurocognitive Rights and Advanced Neurotechnology Act represents an essential and timely legislative framework to address unprecedented advances in neurotechnology that can access, monitor, and potentially manipulate the human brain—the most intimate domain of human existence and the foundation of personal autonomy.

In the current geopolitical landscape, Australia has a unique opportunity to establish itself as a regional and global leader in neurotechnology governance, setting distinctive standards that reflect Australian values while positioning the nation as a hub for responsible innovation in this emerging field. This represents a pivotal moment for Australia to exercise its regulatory sovereignty in shaping the development of transformative technologies that align with its democratic principles and commitment to human rights.

Recent developments in computational neuroscience, neural signal processing, and brain modulation technologies have progressed at an exponential rate, far outpacing our legal frameworks. Australian research institutions including the University of Melbourne, University of Sydney, University of Queensland, and CSIRO, alongside Australia-based technology companies and state health services, are developing sophisticated neurotechnologies that operate at specific electromagnetic frequencies and leverage advanced principles to interact with neural systems in ways that conventional technologies cannot.

Australia already faces concrete challenges requiring urgent regulatory response:

1. Australian technology corporations and startups, including Synchron (founded by Australian researchers at the University of Melbourne), have invested significantly in brain-computer interfaces for commercial and medical applications, with minimal oversight regarding privacy and security protocols for neural data.

2. The Therapeutic Goods Administration (TGA) has approved several invasive and non-invasive neurotechnology devices without comprehensive frameworks to evaluate long-term impacts on cognitive autonomy and mental privacy.

3. Venture capital has poured over AUD 600 million into Australian neurotechnology startups in the past five years alone, creating a rapidly expanding market operating in a regulatory vacuum.

4. Early clinical trials within Australian health systems of cognitive enhancement technologies raise profound questions about equitable access and potential creation of cognitive disparities that could undermine Australian social cohesion.

5. International competitors, including the United States, China, and the European Union, are rapidly developing their own neurotechnology capabilities, creating geopolitical imperatives for establishing Australian leadership in ethical standards and governance in the Asia-Pacific region.

6. Without a unified federal approach, states and territories may develop divergent regulatory frameworks, creating fragmentation that would impede innovation and create regulatory complexity across Australia.

The Australian Human Rights Commission has highlighted that neurotechnology poses significant risks to human rights, particularly privacy, freedom of thought, and non-discrimination, yet Australia "has not been particularly active in the regulatory space" despite the country's historical involvement in neurotechnology development, including pioneering work on cochlear implants.

AUSTRALIAN LEGAL AND VALUES FOUNDATION

The Australian Neurocognitive Rights and Advanced Neurotechnology Act builds upon Australia's strong tradition of rights protection while adapting these protections to emerging technological realities. The right to cognitive liberty can be understood as an extension of existing Australian legal protections:

- International human rights treaties to which Australia is a signatory, including the International Covenant on Civil and Political Rights (particularly Articles 17 and 18 concerning privacy and freedom of thought)
- The Privacy Act 1988 (Cth) and the Australian Privacy Principles, which established robust standards for data protection but require enhancement to address the unique challenges of neural data
- Australia's strong medical ethics framework and informed consent requirements under the National Health and Medical Research Council (NHMRC) guidelines
- Common law protections for individual autonomy and bodily integrity
- The foundations established by the Disability Discrimination Act 1992 (Cth), which can be expanded to prevent discrimination based on neural characteristics or neurotechnology access

Distinguished Australian legal scholars and ethicists, including those from the Australian Neuroethics Network and ethics committees at major research institutions, have articulated the need for specific neurorights protections in Australian jurisprudence. Their work demonstrates that traditional privacy doctrines, even those in the Privacy Act, are insufficient to address technologies that can potentially access thoughts, memories, and cognitive processes.

The Australian Human Rights Commission's research on neurotechnology identified that several applications create unique human rights risks, noting that the right to privacy is protected under Article 17 of the International Covenant on Civil and Political Rights, while the right to freedom of thought—which may be manipulated by neurotechnology—is protected under Article 18.

STRATEGIC AUTONOMY AND AUSTRALIAN COMPETITIVENESS

Establishing a comprehensive legal framework for neurotechnology is central to Australia's strategic autonomy objectives and digital sovereignty agenda. Australia must lead in setting ethical standards and regulatory frameworks for neurotechnology development to ensure these technologies advance Australian values of human dignity, privacy, fairness, and the "fair go" ethos.

The Australian Research Council (ARC), National Health and Medical Research Council (NHMRC), CSIRO, and numerous Australian research institutions have invested significantly in neurotechnology research. These investments demonstrate the strategic importance of neurotechnology for Australian scientific leadership and economic development, particularly as part of the nation's innovation agenda.

Without a comprehensive federal regulatory framework, Australia risks:

1. Losing regional technological leadership to nations with fewer ethical constraints
2. Creating vulnerabilities in neural security that could be exploited by malicious actors
3. Enabling regulatory fragmentation through divergent approaches across states and territories
4. Undermining public trust in legitimate and beneficial applications of neurotechnology
5. Failing to protect the fundamental rights of Australian citizens in an emerging technological domain
6. Losing competitive advantage in the burgeoning neurotechnology industry to jurisdictions with clearer regulatory frameworks

The Australian Human Rights Commission has recommended that Australia should modernize its approach to AI regulation, including technologies that combine AI with neurotechnology, noting that Australia must build upon existing legislation and address shortfalls through AI-specific legislation.

ECONOMIC AND INNOVATION BENEFITS

The neurotechnology sector represents a significant growth opportunity for the Australian economy. According to market analyses, the global neurotechnology market is projected to reach AUD 40 billion by 2027, with Australia positioned to capture a substantial portion of this growth through its strong research base, world-class universities, innovative healthcare system, and dynamic technology sector.

Far from impeding innovation, this legislation will create the regulatory certainty needed for responsible investment and development. By establishing clear guidelines, certification processes, and specialized regulatory oversight, the Act will:

1. Provide regulatory clarity that encourages long-term investment across Australia
2. Create harmonized standards that facilitate interoperability and sector growth

3. Build public trust necessary for widespread adoption of beneficial neurotechnologies
4. Establish Australia as a regional and global leader in ethical neurotechnology development
5. Position Australian companies advantageously in global markets through first-mover advantages in ethical neurotechnology
6. Advance Australia's Medical Research Future Fund objectives for neurological health innovations

Companies developing neurotechnology applications for healthcare, education, entertainment, and productivity will benefit from clear rules of engagement, reducing legal uncertainty and liability exposure. The Australian Neurotechnology Commission established by this legislation will develop expertise necessary to oversee this complex technical domain efficiently, reducing regulatory uncertainty and promoting innovation.

Australia's unique position as a leader in medical research, combined with its strong regulatory traditions and reputation for technological innovation, creates an opportunity to establish a distinctive "Australian approach" to neurotechnology governance that could become a template for other nations, particularly in the Asia-Pacific region.

SPECIALIZED REGULATORY FRAMEWORK: A NECESSARY INNOVATION

The establishment of the Australian Neurotechnology Commission and specialized regulatory mechanisms for neurocognitive rights responds to the unprecedented challenges posed by neurotechnology. These specialized mechanisms build upon Australian precedents:

- The specialized expertise of the Therapeutic Goods Administration for medical technologies
- The Office of the Australian Information Commissioner's expertise in complex privacy matters
- The specialized regulatory approaches of bodies like the Australian Communications and Media Authority
- Australia's tradition of developing independent statutory authorities to address novel technical challenges

Specialized regulatory expertise with technical knowledge has proven effective in these domains, and neurotechnology presents even greater technical complexities that require specialized knowledge. Conventional regulatory approaches lacking neuroscientific and technical expertise risk inconsistent outcomes that could either stifle innovation through overly restrictive interpretations or fail to adequately protect fundamental rights through insufficient scrutiny.

The Australian Human Rights Commission's research on neurotechnology found that these technologies can collect sensitive neural information with significant risk to privacy, and that brain-computer interfaces facilitate bi-directional communication between the brain and external devices, either transmitting neural data or potentially altering neural activity.

As noted by Australian legal and ethical scholars, regulators and judiciary face unprecedented challenges in evaluating evidence related to emerging technologies that can potentially interfere with mental autonomy and cognitive privacy. The creation of a specialized neurotechnology commission would establish Australia as a regional pioneer in neurocognitive governance—an area that will inevitably become central in coming decades.

GLOBAL LEADERSHIP AND STANDARD-SETTING

Australia has historically led in establishing regulatory frameworks for emerging technologies, from early legislation on reproductive technologies to more recent frameworks for gene technology and digital health. Neurotechnology represents the next frontier requiring Australian leadership.

Several nations are moving forward with neurorights protections:

- Chile amended its constitution to explicitly protect neural rights
- Spain and the United States have developed legislative frameworks for neurotechnology regulation
- The European Union is considering neural data protections within its broader AI and data governance agenda
- Various international organizations including UNESCO are developing ethical frameworks for neurotechnology

By enacting comprehensive legislation now, Australia can establish regional standards aligned with Australian values of human dignity, privacy, and individual liberty, while promoting responsible innovation. Failure to act would cede leadership to other nations or regions whose frameworks may not prioritize these values to the same degree.

Australia has consistently demonstrated that well-designed regulation can become a regional standard, particularly in the Asia-Pacific region. A comprehensive Australian framework for neurocognitive rights could similarly shape regional and global practices in neurotechnology development and deployment, creating a distinctive "Australian model" of neurotechnology governance that balances innovation, rights protection, and public benefit.

CROSS-PARTY APPEAL

The Australian Neurocognitive Rights and Advanced Neurotechnology Act transcends traditional political divides, offering compelling justifications for support across the political spectrum:

For conservatives, the Act protects traditional values of human dignity, individual liberty, and autonomy from technological overreach while promoting national security.

For progressives, the Act establishes equity guarantees ensuring that neurotechnology benefits are widely accessible through the public health system while preventing new forms of discrimination.

For national security advocates, the Act establishes frameworks essential for maintaining Australian technological sovereignty and protecting against potential neurocognitive threats.

For business interests, the Act creates regulatory certainty and public trust necessary for the flourishing of a vibrant neurotechnology sector throughout Australia.

For federalism advocates, the Act demonstrates the capacity for national cooperation on complex emerging challenges while respecting the competencies of states and territories.

ALIGNMENT WITH EXISTING AUSTRALIAN PRIORITIES

The Australian Neurocognitive Rights and Advanced Neurotechnology Act aligns perfectly with existing Australian strategic priorities:

- Australia's Digital Economy Strategy 2030
- The Medical Research Future Fund priorities
- The National Innovation and Science Agenda
- Australia's commitment to ethical AI development in the AI Ethics Framework
- The government's focus on advanced manufacturing and technological sovereignty
- The National Health Priority Areas, particularly regarding mental health and neurological conditions

By addressing neurotechnology within a comprehensive regulatory framework, Parliament would demonstrate coherence and foresight in its approach to technological governance, building upon Australia's existing strengths in medical research and healthcare innovation.

DISTINCTIVE AUSTRALIAN APPROACH TO NEUROTECHNOLOGY GOVERNANCE

This legislation offers an opportunity to create a distinctively Australian approach to neurotechnology governance, drawing on the nation's unique strengths:

- Australia's pragmatic regulatory tradition that balances innovation with protection
- Australia's world-class healthcare system with its strong ethical frameworks
- The Australian tradition of balanced and proportionate regulation
- Australia's historical leadership in medical innovation, particularly in neuroscience
- Australia's strong democratic traditions and commitments to individual rights
- Australia's unique position bridging Western democratic values and Asia-Pacific priorities

This approach will offer an alternative to both the more prescriptive European regulatory model and the more market-oriented American approach, positioning Australia as an attractive middle ground for global neurotechnology development, particularly for the Asia-Pacific region.

The Australian Human Rights Commission has identified that although neurotechnologies may be beneficial, if not developed and deployed ethically, human rights risks will occur—particularly to privacy, non-discrimination, and freedom of thought.

CONCLUSION

The Australian Neurocognitive Rights and Advanced Neurotechnology Act represents essential legislation for the emerging era of advanced neurotechnology. By establishing fundamental neurocognitive rights, creating appropriate regulatory frameworks, ensuring proper neural data protections, and establishing specialized regulatory expertise, this legislation will protect the most intimate domain of human autonomy while enabling responsible innovation.

The window for establishing these protections is narrowing as neurotechnology advances at an accelerating pace. By acting decisively now, Parliament has the opportunity to establish landmarks in the protection of human dignity for the digital age.

This legislation will position Australia as a regional and global leader in ethical neurotechnology development and neurocognitive rights protection—upholding Australia's commitment to human dignity, privacy, and fundamental rights in the face of unprecedented technological capabilities to access and influence the human mind.

The time for action is now, before potentially invasive technologies become widespread and before international standards are set by nations or regions that may not share Australia's commitment to fundamental rights and human dignity. We urge Parliament to prioritize passage of this vital legislation to secure cognitive liberty for current and future generations of Australian citizens and to establish Australia as a global leader in responsible neurotechnology innovation.

By implementing this comprehensive legislative framework, Australia can continue its proud tradition of combining technological innovation with ethical governance, ensuring that neurotechnology develops in ways that respect human dignity, promote equitable access, and advance the common good for all Australians.

EXECUTIVE SUMMARY OF THE AUSTRALIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

This comprehensive legislation represents a landmark achievement in the governance of neurotechnology and the protection of neurocognitive rights in Australia. The Act addresses a critical regulatory gap, as Australia currently lacks a specific framework for neurotechnology despite significant involvement in the field.

Key Accomplishments:

1. **Establishing Fundamental Neurocognitive Rights** - The Act recognizes and protects five fundamental neurocognitive rights: cognitive liberty, mental privacy, mental integrity, psychological continuity, and equal access/non-discrimination.

2. **Creating a Risk-Based Regulatory Framework** - Implements a tiered regulatory approach proportionate to the level of risk posed by different neurotechnologies, balancing innovation with safety and rights protection.

3. **Establishing the Australian Neurotechnology Commission** - Creates a dedicated independent regulatory body with specialized expertise and authority to oversee neurotechnology development and use.

4. **Comprehensive Coverage** - Addresses the full spectrum of neurotechnology applications across medical, consumer, research, educational, workplace, security, and military domains.

5. **Promoting Ethical Innovation** - Balances regulatory requirements with support for responsible innovation through guidance, incentives, and regulatory sandboxes.

6. **International Leadership** - Positions Australia as a global leader in ethical neurotechnology governance while aligning with international developments.

This legislation responds proactively to the unprecedented challenges posed by technologies that directly interface with the brain and nervous system. By establishing clear rights, regulatory pathways, and governance mechanisms, the Act creates a foundation for responsible neurotechnology development that respects human dignity, autonomy, and equality while enabling beneficial innovation.

The Act's principles-based approach, coupled with adaptable regulatory mechanisms, ensures the framework can evolve alongside rapid technological advancement, providing both certainty for stakeholders and flexibility for future developments.

THE AUSTRALIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

PART 1: LEGISLATIVE FRAMEWORK

A Bill for an Act

To establish comprehensive protections for neurocognitive rights, regulate advanced neurotechnologies, establish specialized regulatory frameworks and judicial mechanisms for adjudicating cases involving neurocognitive rights, and for other purposes.

Bill Structure

This comprehensive legislation follows the standard Australian federal bill structure, beginning with a long title, followed by enacting words, short title, commencement provisions, purpose provisions, definitions, substantive provisions organized by parts and divisions, and concluding with transitional and administrative provisions.

Explanatory Memorandum

The Neurocognitive Rights and Advanced Neurotechnology Act 2025 aims to establish Australia as a global leader in the ethical development, deployment, and governance of neurotechnology while establishing fundamental protections for neurocognitive rights. This Act recognizes that neurotechnology has the potential to revolutionize healthcare, communication, and human capabilities, but also presents unprecedented challenges to human autonomy, privacy, identity, and equality that current regulatory frameworks are inadequate to address.

Australia currently lacks a specific regulatory framework for neurotechnology despite the country's significant involvement in the field, including pioneering work on cochlear implants and companies like Synchron developing brain-computer interfaces. The Australian Human Rights Commission has already identified key human rights risks associated with neurotechnology, particularly regarding privacy, non-discrimination, and freedom of thought.

This legislation establishes comprehensive neurocognitive rights protections, creates regulatory frameworks for advanced neurotechnologies across medical and non-medical domains, establishes governance mechanisms including a dedicated Neurotechnology Commission, and implements robust enforcement provisions while promoting ethical innovation in the field.

PART 2: THE BILL

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

THE AUSTRALIAN NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

A Bill for an Act to establish comprehensive protections for neurocognitive rights, regulate advanced neurotechnologies, establish specialized regulatory frameworks and judicial mechanisms for adjudicating cases involving neurocognitive rights, and for other purposes.

Be it enacted by the King's Most Excellent Majesty, the Senate, and the House of Representatives of the Commonwealth of Australia, as follows:

PART I - PRELIMINARY

1. Short Title

This Act may be cited as the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025.

2. Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Column 1	Column 2
1. Part I and Part II	The day this Act receives the Royal Assent
2. Part III, Divisions 1-3	6 months after this Act receives the Royal Assent
3. Part III, Division 4	12 months after this Act receives the Royal Assent
4. Part IV	6 months after this Act receives the Royal Assent
5. Parts V through X	12 months after this Act receives the Royal Assent
6. Remaining provisions	The day this Act receives the Royal Assent

(2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3. Constitutional Basis

This Act relies on the following constitutional powers: (a) the external affairs power (section 51(xxix)); (b) the corporations power (section 51(xx)); (c) the trade and commerce power (section 51(i)); (d) the communications power (section 51(v)); (e) the intellectual property power (section 51(xviii)); (f) the medical and pharmaceutical benefits power (section 51(xxiiiA)); (g) the implied nationhood power; and (h) any other relevant heads of power under the Constitution.

4. Objects of the Act

The objects of this Act are:

(a) to establish and protect fundamental neurocognitive rights for all individuals within Australian jurisdiction;

(b) to create a comprehensive regulatory framework for advanced neurotechnologies that balances innovation with safety, efficacy, and ethical considerations;

(c) to establish dedicated regulatory and enforcement mechanisms for neurocognitive rights and neurotechnology;

(d) to promote Australia as a leader in ethical neurotechnology development while ensuring appropriate safeguards are in place;

(e) to address potential systemic inequities in access to neurotechnology and prevent discriminatory applications;

(f) to ensure appropriate governance of neurotechnology across medical and non-medical domains; and

(g) to implement Australia's obligations under international human rights law as they relate to emerging neurotechnologies.

5. Definitions

(1) In this Act, unless the contrary intention appears:

"advanced neurotechnology" means any device, method, or system that directly interfaces with, monitors, records, or modulates the structure or function of the brain or nervous system through electrical, magnetic, optical, acoustic, molecular, or other means, including but not limited to: (a) invasive brain-computer interfaces; (b) non-invasive brain-computer interfaces; (c) neuroimaging technologies; (d) neurostimulation technologies; (e) neural recording technologies; and (f) any other technology directly interacting with neural activity.

"approved neurotechnology device" means an advanced neurotechnology device that has received regulatory approval under Part III of this Act.

"brain data" or **"neural data"** means any information derived directly or indirectly from the measurement, monitoring, or modulation of brain or nervous system activity, including but not limited to: (a) raw neural signals; (b) processed neural information; (c) brain imaging data; (d) brain stimulation parameters and responses; (e) neurophysiological recordings; (f) brain-derived biometric information; and (g) data derived from analysis of neural data.

"Commission" means the Australian Neurotechnology Commission established under Part V of this Act.

"Commissioner" means the Australian Neurotechnology Commissioner appointed under Part V of this Act.

"cognitive liberty" means the right of individuals to autonomous mental self-determination, encompassing both the freedom to control one's own cognitive functions and mental processes and the right to be protected from unwanted modification of those functions.

"dual-use neurotechnology" means advanced neurotechnology that has both medical and non-medical applications, or that could reasonably be used for purposes beyond its intended function.

"high-risk neurotechnology" means advanced neurotechnology that: (a) is invasive; (b) has the capability to write information to the brain or nervous system; (c) has the capability to access, decode, or interpret internal mental states, thoughts, emotions, or intentions; (d) is intended for use in vulnerable populations; (e) is intended for non-medical or enhancement purposes; or (f) is otherwise designated as high-risk by regulations under this Act.

"mental integrity" means the right of an individual to the psychological continuity and authenticity of their mental processes, including protection against unauthorized influence or modulation of neural activity.

"mental privacy" means the right of an individual to control access to and use of their neural data, including protection against unauthorized collection, processing, storage, sharing, or decoding of information derived from their brain or nervous system.

"neuroalgorithm" means any computational method, procedure, or system designed to process, analyze, or interpret neural data.

"neurocognitive rights" means the fundamental rights specific to the protection of the brain, mind, and neural data, including but not limited to: (a) the right to cognitive liberty; (b) the right to mental privacy; (c) the right to mental integrity; (d) the right to psychological continuity; and (e) protection against algorithmic bias and neurotechnology-based discrimination.

"psychological continuity" means the preservation of an individual's self-identity, personal narrative, and sense of agency over time.

"provider" means any person or entity that designs, develops, manufactures, distributes, imports, sells, supplies, implements, or operates advanced neurotechnology in Australia.

"user" means any individual who uses, or is the subject of the use of, advanced neurotechnology.

(2) The Minister may, by legislative instrument, make regulations specifying additional definitions for the purposes of this Act.

PART II - NEUROCOGNITIVE RIGHTS

6. Recognition of Fundamental Neurocognitive Rights

(1) This Act recognizes the following as fundamental neurocognitive rights: (a) The right to cognitive liberty; (b) The right to mental privacy; (c) The right to mental integrity; (d) The right to psychological continuity; and (e) The right to equal neurotechnology access and non-discrimination.

(2) These rights are recognized as extensions of established human rights under Australian and international law.

(3) Neurocognitive rights apply to all individuals within Australian jurisdiction regardless of citizenship or residency status.

(4) The Commission shall develop detailed guidelines on the interpretation and application of these rights within 12 months of its establishment.

7. Right to Cognitive Liberty

(1) Every individual has the right to cognitive liberty, which includes: (a) The right to autonomous mental self-determination; (b) The freedom to control and modify one's own cognitive processes within legal boundaries; (c) The right to refuse brain monitoring, stimulation, or modification; and (d) Protection against coerced or deceptive use of neurotechnology.

(2) Limitations on cognitive liberty may only be imposed: (a) In accordance with law; (b) For legitimate purposes including protection of public health, public safety, the rights of others, or national security; and (c) When demonstrably necessary and proportionate to achieve those purposes.

(3) Any limitation must be subject to appropriate safeguards, oversight, and review mechanisms.

8. Right to Mental Privacy

(1) Every individual has the right to mental privacy, which includes: (a) Control over the collection, use, processing, storage, and transfer of their neural data; (b) Protection against unauthorized access to or decoding of neural information, including thoughts, emotions, memories, or intentions; (c) The right to know when and how their neural data is being collected and processed; and (d) The right to access, correct, and delete neural data collected from them, subject to reasonable exceptions.

(2) Neural data shall be recognized as a special category of sensitive personal information, receiving the highest level of protection under Australian privacy and data protection laws.

(3) Neural data collected for one purpose shall not be used for other incompatible purposes without explicit, informed, and voluntary consent.

9. Right to Mental Integrity

(1) Every individual has the right to mental integrity, which includes: (a) Protection against unauthorized modulation or manipulation of neural activity; (b) The right to the psychological and functional integrity of their cognitive processes; and (c) Protection against forced or covert neurotechnological interventions.

(2) Any intervention that may affect mental integrity must be: (a) Based on valid informed consent, except in narrowly defined emergency circumstances; (b) Performed only for legitimate purposes; (c) Conducted with appropriate safeguards; and (d) Subject to rigorous oversight.

10. Right to Psychological Continuity

(1) Every individual has the right to psychological continuity, which includes: (a) The preservation of personal identity and sense of self; (b) Protection against severe or disruptive alteration of personality, memories, or core psychological attributes through neurotechnological intervention; and (c) The right to maintain control over one's personal narrative and autobiographical memories.

(2) Any neurotechnological intervention with potential to affect psychological continuity must: (a) Be undertaken only with rigorous informed consent protocols; (b) Include comprehensive pre-intervention counseling and assessment; (c) Incorporate monitoring of psychological impacts during and after intervention; and (d) Provide access to remediation or reversal where technically feasible.

11. Right to Equal Neurotechnology Access and Non-Discrimination

(1) All individuals have the right to: (a) Equal access to beneficial neurotechnology for medical purposes; (b) Protection against discrimination based on neurotechnological

assessment or modification status; and (c) Protection against the use of neurotechnology to reinforce or exacerbate existing patterns of discrimination or inequality.

(2) The government shall: (a) Promote equitable access to medically necessary neurotechnology; (b) Prohibit the use of neural data or neurotechnology for discriminatory purposes; (c) Prevent the development of neurotechnology in ways that systematically disadvantage or harm marginalized groups; and (d) Ensure appropriate accommodations for neurodiversity in neurotechnology design and implementation.

12. Additional Protections for Vulnerable Populations

(1) Enhanced protections apply to the use of neurotechnology with: (a) Children and adolescents under 18 years of age; (b) Individuals with cognitive impairments that may affect capacity for informed consent; (c) Individuals in institutional settings, including medical facilities, correctional institutions, and military contexts; (d) Individuals experiencing acute mental health crises; and (e) Other vulnerable groups as identified in regulations.

(2) For these populations: (a) Stringent consent requirements and safeguards shall apply; (b) Independent oversight shall be mandatory for neurotechnology use; (c) Representation of interests through appropriate advocates shall be ensured; and (d) Regular review of continued appropriateness of neurotechnology use shall be required.

(3) The Commission shall develop specific guidelines for neurotechnology use with vulnerable populations within 12 months of its establishment.

PART III - REGULATION OF ADVANCED NEUROTECHNOLOGY

Division 1 - Regulatory Framework

13. Scope of Regulatory Authority

(1) This Part establishes a comprehensive regulatory framework for all advanced neurotechnology within Australian jurisdiction, including: (a) Medical neurotechnology subject to therapeutic goods regulation; (b) Non-medical neurotechnology for consumer, commercial, research, educational, or other purposes; (c) Neurotechnology software, algorithms, and applications; (d) Neural data collection, processing, storage, and transfer systems; and (e) Emerging and future neurotechnologies not yet developed or deployed.

(2) The regulatory framework shall operate: (a) In coordination with existing regulatory systems where appropriate; (b) Through supplementary requirements where existing systems are insufficient for neurotechnology-specific concerns; and (c) Through standalone neurotechnology-specific regulation where necessary.

14. Classification of Neurotechnology

(1) Advanced neurotechnology shall be classified according to: (a) Risk level (low, moderate, high, or critical risk); (b) Invasiveness (non-invasive, minimally invasive, or invasive); (c) Functionality (monitoring/recording, stimulation/modulation, or bidirectional); (d) Purpose (medical therapeutic, medical diagnostic, disability accommodation, research, consumer, military, security, or other); (e) Target population (general adult, vulnerable populations, or specific populations); and (f) Neural data handling capabilities.

(2) The Commission shall develop and maintain detailed classification guidelines.

(3) Classification shall determine: (a) The applicable regulatory pathway; (b) Required evidence standards; (c) Review procedures; (d) Monitoring requirements; and (e) Permitted use contexts.

15. Risk-Based Regulatory System

(1) A tiered, risk-based regulatory system shall apply to all neurotechnology: (a) Low-risk neurotechnology shall be subject to baseline requirements including registration, safety standards, labeling requirements, and post-market surveillance; (b) Moderate-risk neurotechnology shall additionally require pre-market assessment, technical standards certification, data protection protocols, and regular reporting; (c) High-risk neurotechnology shall additionally require comprehensive pre-market approval, clinical or performance evidence, enhanced monitoring, regular recertification, and specialized use constraints; and (d) Critical-risk neurotechnology shall additionally require exceptional justification, parliamentary approval for certain classes, ethics committee oversight, and may be subject to moratoriums in specific contexts.

(2) The Commission shall develop detailed guidelines for each risk tier.

Division 2 - Approval Process

16. Registration Requirements

(1) All advanced neurotechnology must be registered with the Commission before being marketed, sold, or implemented in Australia.

(2) Registration requirements include: (a) Disclosure of technical specifications; (b) Risk assessment; (c) Intended use declaration; (d) Privacy and security measures; (e) Neurocognitive rights impact assessment; and (f) Proposed monitoring and update procedures.

(3) Registration information shall be maintained in a public registry with appropriate protection for legitimate commercial confidentiality.

17. Pre-Market Approval Requirements

(1) High-risk and critical-risk neurotechnology require comprehensive pre-market approval.

(2) Approval requirements include: (a) Evidence of safety through appropriate testing and trials; (b) Evidence of effectiveness for intended purpose; (c) Risk management plans; (d) Neural data governance protocols; (e) Neurocognitive rights impact assessment; (f) User information and consent protocols; and (g) Post-market surveillance plans.

(3) The Minister may, by legislative instrument, specify additional approval requirements for specific types of neurotechnology.

18. Expedited Approval Pathways

(1) Expedited approval pathways may be established for: (a) Medical neurotechnology addressing serious unmet needs; (b) Significant innovations providing substantial benefits over existing options; (c) Neurotechnology specifically designed for rare conditions; and (d) Temporary approval for emergency use.

(2) Expedited pathways must maintain appropriate safety and effectiveness standards while reducing procedural barriers and timeframes.

19. Post-Approval Monitoring

(1) All approved neurotechnology is subject to ongoing monitoring requirements including: (a) Regular safety and performance reporting; (b) Adverse event reporting; (c) Periodic recertification for high-risk and critical-risk technologies; (d) Update and patch management; and (e) User feedback collection and response.

(2) The Commission may require modifications, additional safeguards, or approval withdrawal based on post-approval monitoring findings.

Division 3 - Standards and Requirements

20. Technical Standards

(1) The Commission shall develop, adopt, or recognize technical standards for neurotechnology covering: (a) Safety parameters; (b) Performance metrics; (c) Interoperability requirements; (d) Data formats and protocols; (e) Security requirements; and (f) User interface guidelines.

(2) Standards shall be developed in consultation with: (a) Technical experts; (b) Healthcare professionals; (c) Industry representatives; (d) Consumer advocates; (e) Ethics specialists; and (f) International standards organizations.

(3) Standards shall be periodically reviewed and updated to reflect technological advances and emerging evidence.

21. Neural Data Governance

(1) Neural data governance requirements include: (a) Purpose limitation; (b) Data minimization; (c) Storage limitation; (d) Enhanced security measures; (e) Access controls and audit trails; (f) Prohibition on certain forms of transfer or commercialization; and (g) Special protections for sensitive neural information.

(2) Neural data must be classified according to sensitivity levels, with corresponding protection requirements.

(3) Neural data governance shall operate in coordination with the Privacy Act 1988 (Cth) and other relevant data protection laws.

22. Informed Consent Requirements

(1) Advanced neurotechnology requiring direct interaction with a user's brain or nervous system may only be used with valid informed consent.

(2) Valid informed consent requires: (a) Disclosure of the nature and purpose of the neurotechnology; (b) Explanation of known and potential risks; (c) Description of expected benefits; (d) Details of neural data collection and use; (e) Information about alternatives where relevant; (f) Explanation of user rights and recourse; and (g) Opportunity for questions and clarification.

(3) Enhanced consent requirements apply to high-risk and critical-risk neurotechnology, including: (a) Staged consent processes; (b) Cooling-off periods; (c) Comprehension

verification; (d) Independent consent verification for vulnerable populations; and (e) Ongoing consent renewal for long-term use.

(4) Exceptions to consent requirements are strictly limited to: (a) Genuine medical emergencies where consent cannot reasonably be obtained; (b) Specific research contexts with appropriate ethics approval and safeguards; and (c) Other narrow exceptions explicitly authorized by law and subject to strict oversight.

23. Labeling and Disclosure Requirements

(1) All advanced neurotechnology must include clear, accessible labeling and disclosure covering: (a) Functionality and intended use; (b) Risk information; (c) Neural data practices; (d) User rights; (e) Limitations and contraindications; and (f) Support and recourse information.

(2) Enhanced disclosure requirements apply for high-risk neurotechnology.

(3) The Commission shall develop standardized disclosure formats and requirements.

Division 4 - Special Categories of Neurotechnology

24. Medical Neurotechnology

(1) Medical neurotechnology shall be regulated in coordination with the Therapeutic Goods Administration.

(2) Additional requirements beyond standard therapeutic goods regulation include: (a) Specific neurocognitive rights protections; (b) Enhanced neural data governance; (c) Neurotechnology-specific risk assessment; and (d) Long-term monitoring of psychological impacts.

(3) The Commission and the Therapeutic Goods Administration shall establish a coordinated approval and monitoring system for medical neurotechnology.

25. Consumer Neurotechnology

(1) Consumer neurotechnology, including wearable devices, entertainment applications, and wellness products, must: (a) Meet baseline safety standards; (b) Provide clear and accurate information about capabilities and limitations; (c) Implement appropriate neural data protections; (d) Include safeguards against misuse; and (e) Comply with truth in advertising requirements specific to neurotechnological claims.

(2) Prohibited consumer applications include: (a) Covert or non-consensual neural monitoring; (b) Applications designed to addict or manipulate users; (c) Applications making false or misleading claims about capabilities; and (d) Applications posing significant risks to mental health or development.

26. Neurotechnology in Education

(1) Educational neurotechnology must: (a) Be appropriate for the developmental stage of the target population; (b) Implement enhanced protections for children's neural data; (c) Avoid reinforcing educational inequalities; (d) Respect student autonomy; and (e) Be transparent to parents, guardians, and age-appropriate students about capabilities and limitations.

(2) Educational institutions must: (a) Establish clear policies on neurotechnology use; (b) Ensure appropriate consent processes; (c) Maintain oversight of neurotechnology implementation; and (d) Monitor impacts on student well-being and educational outcomes.

27. Workplace Neurotechnology

(1) Workplace neurotechnology must: (a) Be used only with valid informed consent of workers; (b) Be used only for legitimate and specified workplace purposes; (c) Respect worker privacy and dignity; (d) Not be used for discriminatory purposes; and (e) Be subject to collective bargaining where applicable.

(2) Prohibited workplace applications include: (a) Mandatory brain monitoring unrelated to safety-critical functions; (b) Neural data collection for performance evaluation without explicit consent and clear parameters; (c) Covert or deceptive neural monitoring; and (d) Applications that undermine worker autonomy or create excessive power imbalances.

28. Research Neurotechnology

(1) Research involving neurotechnology must: (a) Obtain approval from an appropriate ethics committee; (b) Implement rigorous informed consent procedures; (c) Minimize risks to participants; (d) Establish clear neural data governance plans; and (e) Report adverse events promptly.

(2) Special protections apply to research with vulnerable populations.

(3) Research results derived from neurotechnology must be: (a) Shared with participants where appropriate; (b) Reported accurately, including limitations; and (c) Made available to benefit the broader community where possible.

29. Law Enforcement and Security Applications

(1) Neurotechnology for law enforcement or security purposes may only be used: (a) Pursuant to specific legislative authorization; (b) With appropriate judicial oversight; (c) When necessary and proportionate to a legitimate aim; (d) With appropriate safeguards against misuse; and (e) Subject to regular independent review.

(2) Prohibited applications include: (a) Compelled brain-based lie detection or memory retrieval; (b) Mass neural surveillance; (c) Neurotechnology-enabled coercion or torture; and (d) Neural data collection without specific authorization.

(3) Neural data collected for law enforcement or security purposes must: (a) Be strictly limited to the authorized purpose; (b) Be retained only for the necessary period; (c) Be protected against unauthorized access; and (d) Be destroyed when no longer necessary for the authorized purpose.

30. Military Neurotechnology

(1) Development and use of military neurotechnology shall be: (a) Limited to legitimate defense purposes; (b) Consistent with Australia's international obligations; (c) Subject to appropriate parliamentary oversight; and (d) Guided by specific ethical frameworks.

(2) Military personnel subject to neurotechnology shall receive: (a) Comprehensive information about the technology; (b) Appropriate consent procedures recognizing the

military context; (c) Ongoing monitoring and support; and (d) Post-service follow-up and care where appropriate.

(3) The Minister for Defence, in consultation with the Commission, shall develop specific regulations for military neurotechnology.

PART IV - NEUROALGORITHMIC GOVERNANCE

31. Scope of Neuroalgorithmic Governance

(1) This Part establishes governance requirements for algorithms that: (a) Process, analyze, or interpret neural data; (b) Generate synthetic or modified neural data; (c) Control or influence neurotechnology operation; or (d) Make decisions or recommendations based on neural information.

(2) Governance requirements apply to all phases of the algorithmic lifecycle, including: (a) Design and development; (b) Testing and validation; (c) Implementation and use; (d) Monitoring and updating; and (e) Retirement and data disposition.

32. Algorithmic Transparency and Explainability

(1) Neuroalgorithms must incorporate appropriate levels of transparency and explainability, including: (a) Documentation of design principles and intended functions; (b) Explanation of key decision-making factors in user-accessible language; (c) Disclosure of limitations and potential biases; and (d) Traceability of algorithmic outputs.

(2) The required level of transparency and explainability shall be proportionate to: (a) The risk level of the application; (b) The context of use; (c) The potential impact on neurocognitive rights; and (d) Technical feasibility.

33. Algorithmic Impact Assessments

(1) High-risk neuroalgorithms require algorithmic impact assessments covering: (a) Potential impacts on neurocognitive rights; (b) Risks of bias or discrimination; (c) Security vulnerabilities; (d) Unintended consequences; and (e) Mitigation strategies.

(2) Impact assessments must be: (a) Conducted by qualified personnel; (b) Documented and retained; (c) Updated periodically and after significant changes; and (d) Made available to the Commission upon request.

34. Algorithmic Auditing and Testing

(1) High-risk and critical-risk neuroalgorithms require: (a) Pre-implementation testing across diverse populations; (b) Evaluation for potential biases; (c) Performance verification across intended use contexts; and (d) Regular post-implementation auditing.

(2) The Commission may require: (a) Independent third-party auditing; (b) Access to training data and methodologies; and (c) Performance benchmarking against established standards.

35. Human Oversight Requirements

(1) Critical decisions based on neuroalgorithmic processing require appropriate human oversight, including: (a) Review of algorithmic recommendations before implementation;

(b) Ability to override algorithmic decisions; (c) Access to explanations of algorithmic outputs; and (d) Regular evaluation of algorithmic performance.

(2) The level of required human oversight shall be proportionate to: (a) The potential impact of decisions; (b) The risk level of the application; (c) The reliability of the algorithm; and (d) The context of use.

36. Neurofeedback and Autonomous Systems

(1) Systems incorporating autonomous neurofeedback or closed-loop neural modulation must: (a) Include appropriate safety mechanisms; (b) Maintain audit trails of system actions; (c) Incorporate user override capabilities where feasible; (d) Include regular human monitoring; and (e) Meet enhanced technical standards specific to autonomous neural systems.

(2) The Commission shall develop specific guidelines for autonomous neurotechnology systems.

PART V - INSTITUTIONAL FRAMEWORK

37. Establishment of the Australian Neurotechnology Commission

(1) This section establishes the Australian Neurotechnology Commission as an independent statutory authority.

(2) The Commission shall: (a) Regulate advanced neurotechnology in accordance with this Act; (b) Protect and promote neurocognitive rights; (c) Monitor emerging neurotechnology developments; (d) Provide guidance to government, industry, and the public; and (e) Coordinate with other regulatory bodies on neurotechnology matters.

(3) The Commission shall have operational independence while maintaining appropriate parliamentary accountability.

38. Composition of the Commission

(1) The Commission shall consist of: (a) The Neurotechnology Commissioner, who shall chair the Commission; (b) The Deputy Neurotechnology Commissioner; (c) 3-5 additional Commissioners with expertise in neuroscience, ethics, law, technology, medicine, and/or consumer protection; and (d) Advisory committees as established under section 41.

(2) Commissioners shall be appointed by the Governor-General on recommendation of the Minister.

(3) Appointments shall: (a) Be based on relevant expertise and experience; (b) Ensure diversity of perspective and background; (c) Include representation or expertise regarding vulnerable populations; and (d) Be for terms of 5 years, with the possibility of reappointment for one additional term.

39. Powers and Functions of the Commission

(1) The Commission's powers and functions include: (a) Developing and implementing regulations, standards, and guidelines under this Act; (b) Reviewing and approving advanced neurotechnology; (c) Monitoring compliance with neurocognitive rights protections; (d) Investigating potential violations; (e) Enforcing requirements through available mechanisms; (f) Advising government on neurotechnology policy; (g) Promoting

public awareness and education; (h) Facilitating stakeholder consultation and engagement; (i) Conducting and commissioning research; (j) Representing Australia in international neurotechnology governance forums; and (k) Any other functions conferred by this Act or regulations.

(2) In exercising its powers and functions, the Commission shall: (a) Act independently and in the public interest; (b) Base decisions on scientific evidence and ethical principles; (c) Consult with relevant stakeholders; and (d) Apply a proportionate and risk-based approach.

40. Reporting and Accountability

(1) The Commission shall: (a) Submit an annual report to Parliament on its activities, findings, and recommendations; (b) Appear before relevant parliamentary committees when requested; (c) Maintain a public register of approved neurotechnology; (d) Publish guidance materials, standards, and significant decisions; and (e) Operate with transparency while protecting legitimate confidentiality.

(2) The operation of the Commission shall be subject to review: (a) By the relevant parliamentary committee every 3 years; and (b) By independent review every 6 years.

41. Advisory Committees

(1) The Commission shall establish the following advisory committees: (a) Scientific and Technical Advisory Committee; (b) Ethics and Rights Advisory Committee; (c) Consumer and Public Interest Advisory Committee; and (d) Industry and Innovation Advisory Committee.

(2) Each committee shall: (a) Provide expert advice within its domain; (b) Include diverse representation; (c) Meet regularly as determined by the Commission; and (d) Publish summaries of its advice and recommendations.

(3) The Commission may establish additional specialized advisory committees as needed.

42. Coordination with Other Regulatory Bodies

(1) The Commission shall establish formal coordination mechanisms with: (a) The Therapeutic Goods Administration; (b) The Office of the Australian Information Commissioner; (c) The Australian Human Rights Commission; (d) The Australian Communications and Media Authority; (e) The Australian Competition and Consumer Commission; and (f) Other relevant regulatory bodies.

(2) Coordination mechanisms shall address: (a) Jurisdictional boundaries; (b) Information sharing; (c) Joint investigations where appropriate; (d) Consistent application of requirements; and (e) Regulatory efficiency and reduced duplication.

PART VI - COMPLIANCE AND ENFORCEMENT

43. Monitoring and Investigation Powers

(1) The Commission has powers to: (a) Monitor compliance with this Act and regulations; (b) Investigate potential violations; (c) Require production of information and documents; (d) Inspect premises with consent or warrant; (e) Test or examine neurotechnology; and (f) Issue compliance notices.

(2) Authorized officers of the Commission may: (a) Enter premises with consent or warrant; (b) Search for and examine relevant items; (c) Take samples or copies; (d) Use equipment on premises; and (e) Interview relevant persons.

44. Civil Enforcement

(1) The Commission may issue: (a) Improvement notices requiring specific actions to address non-compliance; (b) Prohibition notices preventing specific activities that create serious risks; (c) Infringement notices for specified violations; and (d) Enforceable undertakings.

(2) The Commission may apply to the Federal Court for: (a) Injunctions to prevent violations; (b) Orders for remedial action; (c) Compensation orders for affected individuals; and (d) Civil penalties for violations.

(3) Maximum civil penalties are: (a) For individuals: 5,000 penalty units; (b) For corporations: the greater of 50,000 penalty units or 10% of annual turnover.

45. Criminal Offenses

(1) Criminal offenses under this Act include: (a) Knowing or reckless violations that create serious risk of harm; (b) Unauthorized access to or manipulation of neural data; (c) Covert or non-consensual use of neurotechnology except as lawfully authorized; (d) Provision of false or misleading information in regulatory submissions; and (e) Obstruction of the Commission in the exercise of its functions.

(2) Penalties for criminal offenses include: (a) For individuals: imprisonment for up to 7 years, fines of up to 10,000 penalty units, or both; (b) For corporations: fines of up to 100,000 penalty units.

(3) Criminal proceedings may only be instituted with the consent of the Director of Public Prosecutions.

46. Individual Remedies

(1) Individuals whose neurocognitive rights are violated may: (a) Lodge a complaint with the Commission; (b) Apply for compensation under applicable schemes; (c) Pursue civil remedies through courts; and (d) Seek injunctive relief to prevent ongoing violations.

(2) The Commission may assist individuals in pursuing remedies, including through: (a) Advice and information; (b) Investigation of complaints; (c) Alternative dispute resolution facilitation; and (d) Legal action on behalf of affected individuals in significant cases.

47. Specialized Adjudication

(1) The Administrative Appeals Tribunal shall establish a Neurotechnology Division with specialized expertise to review: (a) Commission decisions regarding approval or restriction of neurotechnology; (b) Neural data protection determinations; (c) Classification decisions; and (d) Other reviewable decisions under this Act.

(2) The Federal Court shall develop specialized procedures for neurocognitive rights cases, including: (a) Expedited proceedings for urgent matters; (b) Modified evidence rules appropriate for neurotechnology contexts; (c) Expert assessors to assist the court; and (d) Appropriate confidentiality protections.

PART VII - PROMOTING ETHICAL INNOVATION

48. Ethical Innovation Framework

(1) The Commission shall develop and maintain an Ethical Innovation Framework for neurotechnology that: (a) Identifies ethical principles and values that should guide neurotechnology development; (b) Provides practical guidance on implementing these principles; (c) Establishes processes for ethical assessment at different stages of development; (d) Promotes responsible research and innovation; and (e) Encourages public engagement and participation.

(2) The Framework shall address: (a) Research ethics; (b) Development ethics; (c) Implementation ethics; (d) Ethics of access and distribution; and (e) Governance ethics.

49. Support for Responsible Innovation

(1) The Minister shall establish programs to support responsible neurotechnology innovation, including: (a) Grants for research and development that prioritize ethical considerations; (b) Technical assistance for neurocognitive rights compliance; (c) Guidance materials and tools; (d) Regulatory sandboxes for testing innovative approaches; and (e) Recognition and incentives for exemplary practices.

(2) Support programs shall particularly encourage: (a) Innovations that address unmet medical needs; (b) Technologies that reduce healthcare disparities; (c) Approaches that minimize risks to neurocognitive rights; (d) Participatory design involving affected communities; and (e) Open and collaborative development where appropriate.

50. Australian Neurotechnology Ethics Council

(1) This section establishes the Australian Neurotechnology Ethics Council as an independent body to: (a) Provide ethical guidance on neurotechnology development and use; (b) Advise the Commission on ethical dimensions of regulatory decisions; (c) Promote public discussion and understanding of neuroethical issues; (d) Monitor international developments in neuroethics; and (e) Publish reports and recommendations on ethical issues.

(2) The Council shall consist of 9-15 members appointed by the Minister, representing diverse perspectives including: (a) Ethics and philosophy; (b) Neuroscience; (c) Medicine; (d) Law and human rights; (e) Consumer perspectives; (f) Disability perspectives; (g) Indigenous perspectives; and (h) Technology assessment.

51. Public Engagement and Education

(1) The Commission shall develop and implement a comprehensive public engagement strategy, including: (a) Public education programs on neurotechnology, its potential benefits, risks, and governance; (b) Consultation mechanisms for policy development; (c) Citizen deliberation on significant neurotechnology issues; (d) Accessible information about neurocognitive rights; and (e) Regular public reporting on neurotechnology developments and regulatory activities.

(2) The Commission shall establish a Neurotechnology Futures Forum bringing together diverse stakeholders annually to: (a) Discuss emerging trends and issues; (b) Review

regulatory approaches; (c) Share perspectives on priorities; and (d) Develop recommendations for policy and regulation.

PART VIII - INTERNATIONAL COOPERATION

52. International Engagement

(1) The Minister and the Commission shall actively engage in international forums addressing neurotechnology governance, including: (a) Multilateral organizations; (b) Standard-setting bodies; (c) Scientific collaborations; (d) Human rights mechanisms; and (e) Bilateral and regional partnerships.

(2) Australia shall work toward: (a) Developing harmonized international standards for neurotechnology; (b) Establishing mutual recognition arrangements with comparable jurisdictions; (c) Supporting neural data protection in international frameworks; (d) Advancing neurocognitive rights in international human rights instruments; and (e) Promoting responsible global governance of neurotechnology.

53. International Data Transfers

(1) Neural data may only be transferred internationally when: (a) The destination jurisdiction offers equivalent or stronger protection for neural data; (b) Binding and enforceable safeguards are in place to ensure appropriate protection; (c) The individual has given explicit informed consent for the transfer; or (d) The transfer is necessary for important public interest reasons and includes appropriate safeguards.

(2) The Commission shall: (a) Assess the adequacy of other jurisdictions' neural data protection; (b) Develop standard contractual clauses for international neural data transfers; (c) Approve binding corporate rules for multinational organizations; and (d) Cooperate with international counterparts on neural data protection enforcement.

54. Dual-Use and Security Considerations

(1) The export of specified high-risk or dual-use neurotechnology shall be subject to controls similar to those applicable to sensitive technologies under existing export control regimes.

(2) The Minister shall: (a) Develop a specific neurotechnology export control framework in consultation with relevant security agencies; (b) Participate in international efforts to address security dimensions of neurotechnology; (c) Monitor emerging dual-use applications; and (d) Balance security concerns with legitimate scientific collaboration and commercial activities.

PART IX - REVIEW AND ADAPTATION

55. Technology Assessment and Foresight

(1) The Commission shall establish a Neurotechnology Assessment and Foresight Unit to: (a) Monitor emerging neurotechnology developments; (b) Assess potential impacts on neurocognitive rights and society; (c) Identify regulatory gaps or challenges; (d) Develop scenarios for potential futures; and (e) Recommend policy and regulatory responses.

(2) The Unit shall produce: (a) Annual technology landscape reports; (b) Specific assessments of significant emerging technologies; (c) Policy briefs on regulatory implications; and (d) Long-term foresight reports every 3 years.

56. Regular Review and Amendment

(1) The Minister shall cause a comprehensive review of this Act to be undertaken: (a) Within 3 years of commencement; and (b) At least every 5 years thereafter.

(2) Reviews shall: (a) Assess the effectiveness of the Act in achieving its objects; (b) Identify technological developments requiring regulatory adaptation; (c) Evaluate the performance of institutional arrangements; (d) Consider international developments and best practices; and (e) Recommend amendments or reforms as appropriate.

(3) Review reports shall be: (a) Prepared by independent reviewers; (b) Tabled in Parliament within 15 sitting days of receipt by the Minister; and (c) Published and made available for public comment.

PART X - MISCELLANEOUS

57. Regulations

(1) The Governor-General may make regulations prescribing matters: (a) Required or permitted by this Act to be prescribed; or (b) Necessary or convenient for carrying out or giving effect to this Act.

(2) Without limiting subsection (1), regulations may: (a) Establish specific requirements for different categories of neurotechnology; (b) Prescribe standards, processes, and procedures; (c) Establish fees and charges; (d) Create exemptions or modified requirements for specified circumstances; and (e) Provide for transitional matters.

58. Constitutional Severability

If any provision of this Act would be invalid because it exceeds the Commonwealth's constitutional power, that provision is to be read as limited to the extent necessary to be within power, and if that is not possible, the provision is to be severed, leaving the remainder of the Act operating to the extent constitutionally permitted.

59. Schedules

(1) The operation of each Schedule is subject to the provisions in the main body of this Act.
(2) The provisions of each Schedule have effect accordingly.

60. Consequential Amendments

The Acts specified in Schedule 1 are amended as set out in that Schedule.

SCHEDULE 1 - CONSEQUENTIAL AMENDMENTS

Part 1 - Amendments to the Privacy Act 1988

1. After subsection 6(1), insert: "(1A) In this Act, 'neural data' has the same meaning as in the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025."

2. After paragraph 6FA(2)(c), insert: "(ca) neural data;"

3. After section 26WB, insert: "26WC Notification of neural data breaches (1) If an entity experiences a data breach involving neural data, the entity must, in addition to any requirements under Part IIIC, notify the Australian Neurotechnology Commission within 24 hours of becoming aware of the breach. (2) The notification under subsection (1) must include: (a) the nature of the neural data involved; (b) the number of individuals potentially affected; (c) any specific risks associated with the neural data breach; and (d) steps being taken to mitigate harm."

Part 2 - Amendments to the Therapeutic Goods Act 1989

1. After paragraph 3(1)(e), insert: "(ea) to provide for the regulation of therapeutic devices that interface with the brain or nervous system in coordination with the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025;"
2. After section 41CB, insert: "41CC Neurotechnology devices (1) The Secretary must consult with the Australian Neurotechnology Commission before including a neurotechnology device in the Register. (2) The Secretary may impose conditions on the registration of a neurotechnology device to ensure compliance with the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025. (3) In this section, 'neurotechnology device' means a therapeutic device that meets the definition of 'advanced neurotechnology' under the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025."

Part 3 - Amendments to the Human Rights (Parliamentary Scrutiny) Act 2011

1. After paragraph 3(1)(g), insert: "(ga) the neurocognitive rights recognized in the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025;"

Part 4 - Amendments to Other Acts

[Additional consequential amendments to other relevant legislation would be included here]

SCHEDULE 2 - TRANSITIONAL PROVISIONS

Part 1 - Definitions

1. In this Schedule: "commencement day" means the day on which Part III of this Act commences. "transitional period" means the period of 2 years beginning on the commencement day.

Part 2 - Existing Neurotechnology

2. (1) A person who, immediately before the commencement day, was lawfully manufacturing, supplying, or using advanced neurotechnology may continue to do so during the transitional period. (2) During the transitional period, the person must: (a) register the neurotechnology with the Commission; (b) comply with any interim safety directions issued by the Commission; and (c) apply for approval under Part III if required for continued operation after the transitional period.
3. If a person applies for approval during the transitional period, they may continue to manufacture, supply, or use the neurotechnology until the application is determined, even if this extends beyond the transitional period.

Part 3 - First Appointments to the Commission

4. (1) The first Neurotechnology Commissioner and Deputy Commissioner shall be appointed within 3 months of the Royal Assent. (2) The first appointments of other Commissioners shall be made within 6 months of the Royal Assent. (3) The terms of the first appointments may be staggered to ensure continuity of the Commission.

Part 4 - Initial Regulatory Development

5. (1) The Commission shall develop and publish initial: (a) classification guidelines within 6 months of establishment; (b) technical standards within 9 months of establishment; (c) approval processes within 9 months of establishment; and (d) neural data governance requirements within 12 months of establishment. (2) Until specific standards are developed, the Commission may recognize appropriate international or industry standards as interim measures. (3) The Commission shall conduct public consultation on all initial regulatory instruments. (4) The Minister may issue directions regarding priorities for initial regulatory development.

Part 5 - Early Operation Period

6. (1) During the first 12 months after the commencement of Part III, the Commission shall adopt a primarily advisory and educational approach to enforcement, except in cases of serious risk to safety or rights. (2) The Commission shall provide assistance to affected entities to facilitate compliance during this period.

7. The Commission shall report to Parliament every 6 months during the first 2 years of operation on: (a) progress in implementing this Act; (b) challenges encountered; (c) interim measures adopted; and (d) recommendations for amendments or adjustments to the regulatory framework.

PART XI - EXPLANATORY MEMORANDUM

Division 1 - Background and Context

61. Purpose and Objectives

The Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025 is landmark legislation that addresses the unprecedented challenges and opportunities presented by the rapid advancement of neurotechnology. This Act establishes Australia as a global leader in the ethical governance of neurotechnology while ensuring robust protection of neurocognitive rights.

The Act's primary objectives are:

(1) To establish a comprehensive framework of neurocognitive rights as an extension of fundamental human rights;

(2) To create a balanced regulatory system for neurotechnology that promotes innovation while protecting safety and rights;

(3) To establish institutional structures for effective oversight and governance;

(4) To ensure Australia's regulatory approach aligns with international best practices while reflecting Australian values and legal traditions; and

(5) To promote public engagement and understanding of neurotechnology and its implications.

62. The Need for Specialized Legislation

The unique nature of neurotechnology, which directly interfaces with the brain and nervous system, creates unprecedented regulatory challenges that cannot be adequately addressed through existing frameworks. The neural data generated by these technologies represents an especially sensitive category of personal information that warrants specific protections beyond those provided by general privacy laws.

The capacity of advanced neurotechnology to access, decode, or influence neural processes raises fundamental questions about mental privacy, cognitive liberty, and the nature of human autonomy that require dedicated legal frameworks. As neurotechnology continues to advance rapidly, proactive regulation is essential to guide its development in beneficial directions while preventing potential harms.

63. International Context

This legislation aligns with emerging international approaches to neurotechnology governance, including:

(1) The Chilean constitutional amendment recognizing "neurorights";

(2) The UNESCO framework on the ethics of neurotechnology;

(3) The Council of Europe's work on neurotechnology governance;

(4) Various national initiatives addressing neural data protection; and

(5) Academic and civil society proposals for neurocognitive rights frameworks.

While drawing on these international developments, this Act is tailored to Australia's unique legal, social, and constitutional context.

Division 2 - Key Features of the Act

64. Neurocognitive Rights Framework

The Act establishes five fundamental neurocognitive rights:

(1) The right to cognitive liberty - protecting the autonomy and self-determination of one's own mental processes;

(2) The right to mental privacy - ensuring control over access to and use of neural data;

(3) The right to mental integrity - protecting against unauthorized influence or modulation of neural activity;

(4) The right to psychological continuity - preserving the continuity of personal identity and sense of self; and

(5) The right to equal neurotechnology access and non-discrimination - ensuring equitable access to beneficial neurotechnology and protection against neurotechnology-based discrimination.

These rights are recognized as extensions of established human rights rather than entirely novel constructs, grounding them in existing legal frameworks while acknowledging their unique dimensions.

65. Risk-Based Regulatory Approach

The Act implements a tiered, risk-based regulatory system that applies proportionate requirements based on the level of risk posed by different neurotechnologies. This approach:

(1) Minimizes regulatory burden for low-risk applications;

(2) Applies more stringent requirements as risk increases;

(3) Recognizes both direct risks to individual users and broader societal risks; and

(4) Considers both the inherent characteristics of the technology and its context of use.

66. Comprehensive Coverage

The Act covers the full spectrum of neurotechnology applications, including:

(1) Medical applications such as neural implants, brain stimulation therapies, and diagnostic systems;

(2) Consumer applications including wearable neural monitors and neurofeedback systems;

(3) Research applications;

(4) Educational and workplace applications;

(5) Security and law enforcement applications; and

(6) Military applications.

This comprehensive approach prevents regulatory gaps while allowing for context-appropriate requirements in different domains.

67. Specialized Institutional Framework

The Act establishes the Australian Neurotechnology Commission as an independent statutory authority with specialized expertise and dedicated focus on neurotechnology governance. This approach recognizes that effective regulation requires:

(1) Specialized technical and ethical knowledge;

(2) Flexibility to adapt to rapid technological change;

(3) Cross-sectoral perspective across different application domains; and

(4) Clear accountability and transparency mechanisms.

68. Promotion of Ethical Innovation

The Act balances regulatory requirements with positive support for ethical innovation through:

(1) Clear guidance on compliance pathways;

(2) Support programs for responsible development;

(3) Recognition of exemplary practices; and

(4) Regulatory sandboxes for testing novel approaches.

These measures aim to ensure that regulation enables rather than impedes beneficial innovation.

Division 3 - Implementation and Expected Impact

69. Implementation Approach

The Act will be implemented through a phased approach:

(1) Immediate establishment of the Commission and development of key regulations and standards;

(2) A transitional period allowing existing neurotechnology to adapt to new requirements;

(3) Full implementation of the regulatory framework; and

(4) Ongoing review and adaptation as the technology evolves.

This approach recognizes the need for both regulatory certainty and flexibility in a rapidly evolving field.

70. Expected Benefits

The anticipated benefits of this legislation include:

(1) Enhanced protection of individual rights and interests in relation to neurotechnology;

(2) Increased public trust in neurotechnology through transparent governance;

(3) Regulatory certainty for industry, promoting responsible investment and innovation;

(4) Positioning Australia as a leader in ethical neurotechnology governance; and

(5) Prevention of potential harms from unregulated neurotechnology development.

71. Compliance Costs and Economic Impact

While the Act introduces new regulatory requirements, these have been designed to minimize unnecessary burden through:

(1) Risk-based tiering of requirements;

(2) Alignment with existing regulatory systems where possible;

(3) Clear guidance and support for compliance; and

(4) Phased implementation allowing for adaptation.

Economic impact assessment indicates that the benefits of increased trust, certainty, and harm prevention substantially outweigh the compliance costs. The Act is expected to strengthen Australia's neurotechnology sector by establishing a trusted environment for development and deployment.

72. Review and Adaptation

Recognizing the rapidly evolving nature of neurotechnology, the Act incorporates robust review mechanisms to ensure ongoing effectiveness, including:

(1) Regular statutory reviews;

(2) Continuous technology assessment and foresight;

(3) Stakeholder feedback mechanisms; and

(4) International engagement to align with global best practices.

These mechanisms will ensure the regulatory framework remains appropriate and effective as neurotechnology continues to develop.

PART XII - SPECIFIC PROVISIONS AND PROCEDURAL GUIDELINES

Division 1 - Technical Standards and Requirements

73. Safety and Performance Standards

(1) Safety standards for neurotechnology shall address: (a) Physical safety of hardware components; (b) Electromagnetic compatibility and radiation limits; (c) Biocompatibility for invasive components; (d) Neural stimulation parameters and limits; (e) Heat generation and dissipation; (f) Infection control for invasive devices; (g) Electrical safety; and (h) Failure modes and safety mechanisms.

(2) Performance standards shall address: (a) Accuracy of neural monitoring; (b) Precision of neural stimulation; (c) Reliability and consistency; (d) Latency and response time; (e) Durability and longevity; and (f) Performance degradation patterns.

(3) Standards shall be developed with reference to: (a) International standards where available; (b) Scientific evidence; (c) Clinical experience; and (d) Risk assessment methodologies.

74. Technical Security Requirements

(1) Neurotechnology security requirements shall include: (a) Authentication mechanisms; (b) Access controls; (c) Encryption of neural data; (d) Protection against unauthorized access; (e) Secure update mechanisms; (f) Vulnerability management; (g) Hardware security measures; and (h) System monitoring and anomaly detection.

(2) Security requirements shall be proportionate to: (a) The sensitivity of neural data involved; (b) The potential impact of security breaches; (c) The context of use; and (d) Technical feasibility.

(3) The Commission shall regularly review and update security requirements in response to emerging threats and technological developments.

75. Testing and Validation Requirements

(1) Testing and validation requirements shall include: (a) Laboratory testing protocols; (b) Clinical or performance trials appropriate to the technology type; (c) Real-world performance evaluation; (d) Safety monitoring methodologies; (e) Validation across diverse populations where appropriate; and (f) Usability and human factors assessment.

(2) Evidence requirements shall be proportionate to: (a) Risk level; (b) Novelty of the technology; (c) Intended use context; and (d) Target population.

(3) The Commission shall develop specific guidance on evidence standards for different categories of neurotechnology.

Division 2 - Procedural Guidelines

76. Application Procedures

(1) Applications for neurotechnology approval shall: (a) Be submitted through the Commission's electronic portal; (b) Include all required technical documentation; (c) Be accompanied by the prescribed fee; and (d) Be in the form specified by the Commission.

(2) The Commission shall: (a) Acknowledge receipt within 5 business days; (b) Conduct an initial completeness check within 10 business days; (c) Request any additional information within 20 business days; and (d) Make a determination within timeframes specified in regulations.

(3) Expedited procedures shall be available for: (a) Minor modifications to approved technologies; (b) Emergency medical applications; and (c) Other circumstances specified in regulations.

77. Review and Appeal Procedures

(1) Applicants may request review of Commission decisions within 28 days.

(2) Internal review shall be conducted by a Commission officer not involved in the original decision.

(3) Decisions following internal review may be appealed to the Administrative Appeals Tribunal.

(4) Judicial review remains available under the Administrative Decisions (Judicial Review) Act 1977.

78. Notification and Reporting Requirements

(1) Providers of approved neurotechnology must notify the Commission of: (a) Adverse events within timeframes specified in regulations; (b) Significant

modifications to approved technology; (c) New safety information; (d) Security vulnerabilities discovered; and (e) Changes to manufacturing processes or quality systems.

(2) Periodic reporting requirements include: (a) Annual safety and performance reports; (b) Update on post-market surveillance activities; (c) Summary of complaints and incidents; and (d) Other information specified in regulations.

(3) The Commission shall establish an electronic reporting system to facilitate efficient compliance.

Division 3 - Classification and Categorization Guidelines

79. Risk Classification Methodology

(1) Risk classification shall consider: (a) Invasiveness; (b) Target neural structures; (c) Mechanism of action; (d) Potential for direct harm; (e) Reversibility of effects; (f) Target population vulnerability; (g) Purpose and context of use; (h) Potential for misuse; (i) Neural data sensitivity; and (j) Autonomy of operation.

(2) The Commission shall publish detailed risk classification guidelines, including: (a) Risk assessment methodologies; (b) Classification examples; (c) Borderline case guidance; and (d) Classification determination procedures.

80. Special Categories Guidelines

(1) The Commission shall develop specific guidelines for: (a) Pediatric neurotechnology; (b) Neurotechnology for cognitive or psychiatric conditions; (c) Enhancement neurotechnology; (d) Autonomous or learning systems; (e) Neurotechnology with potential for addiction or dependency; and (f) Other categories identified through regulation.

(2) Guidelines shall address: (a) Additional safety requirements; (b) Enhanced consent procedures; (c) Specialized monitoring; (d) Use limitations; and (e) Other protections appropriate to the category.

Division 4 - Enforcement Guidelines

81. Compliance Monitoring Approach

(1) The Commission shall adopt a compliance monitoring approach that: (a) Is risk-based and proportionate; (b) Uses a range of monitoring techniques; (c) Balances routine monitoring with targeted investigations; (d) Combines self-reporting with independent verification; and (e) Coordinates with other regulatory agencies where appropriate.

(2) Monitoring activities may include: (a) Documentation review; (b) Remote auditing; (c) On-site inspections; (d) Product testing; (e) User experience surveys; and (f) Analysis of reported incidents.

82. Enforcement Decision Framework

(1) The Commission shall develop an enforcement decision framework that: (a) Ensures consistency and proportionality; (b) Considers risk to public safety and

rights; (c) Takes account of compliance history; (d) Escalates responses appropriately; and (e) Balances deterrence with education and assistance.

(2) The framework shall specify: (a) Criteria for different enforcement responses; (b) Decision-making procedures; (c) Review and appeal mechanisms; and (d) Publication of enforcement actions.

83. Voluntary Compliance Mechanisms

(1) The Commission shall establish voluntary compliance mechanisms including: (a) Pre-submission consultations; (b) Compliance assistance programs; (c) Self-assessment tools; (d) Voluntary audit programs; and (e) Recognized quality systems.

(2) Participation in voluntary compliance mechanisms may be considered as a mitigating factor in enforcement decisions.

PART XIII - FURTHER ELABORATION OF NEUROCOGNITIVE RIGHTS

84. Cognitive Liberty: Detailed Application

(1) The right to cognitive liberty encompasses: (a) Freedom from unwanted neural monitoring or surveillance; (b) Protection against coerced or deceptive use of neurotechnology; (c) Autonomous decision-making regarding the use of neurotechnology; (d) Control over one's own cognitive processes and mental states; (e) Protection against manipulation through neurotechnology; and (f) Freedom from stigmatization or discrimination based on neurocognitive characteristics.

(2) In medical contexts, cognitive liberty includes: (a) The right to access beneficial neurotechnology for legitimate medical needs; (b) The right to refuse neurotechnological interventions; (c) Protection against coerced treatment except in narrowly defined circumstances; and (d) Informed participation in treatment decisions.

(3) In research contexts, cognitive liberty includes: (a) Freedom from coerced research participation; (b) The right to comprehensive information before consent; (c) The right to withdraw from research; and (d) Protection against deception regarding neurotechnology capabilities.

(4) In consumer contexts, cognitive liberty includes: (a) Protection against hidden or covert neurotechnology; (b) The right to accurate information about neurotechnology capabilities and limitations; (c) Freedom from manipulative neurotechnology practices; and (d) The right to control and customize neurotechnology interfaces.

85. Mental Privacy: Detailed Application

(1) The right to mental privacy encompasses: (a) Protection against unauthorized access to neural data; (b) Control over the collection, use, and sharing of neural data; (c) Protection against involuntary neural decoding or mind-reading; (d) The right to confidentiality of neural information; and (e) Protection against neural surveillance.

(2) In healthcare contexts, mental privacy includes: (a) Confidentiality of neural data equivalent to other medical information; (b) Purpose limitation for collected neural data; (c) Enhanced security for neural data storage and transmission; and (d) The right to access and request deletion of neural data collected.

(3) In commercial contexts, mental privacy includes: (a) Transparent disclosure of neural data collection practices; (b) Opt-in consent for neural data collection and use; (c) Limitations on secondary uses of neural data; and (d) Protection against discriminatory uses of neural information.

(4) In public and security contexts, mental privacy includes: (a) Prohibition on mass neural surveillance; (b) Strict limitations on government access to neural data; (c) Judicial oversight of neural data collection; and (d) Proportionate and necessary limitations only.

86. Mental Integrity: Detailed Application

(1) The right to mental integrity encompasses: (a) Protection against unauthorized modulation of neural activity; (b) Protection against harmful neurotechnology interventions; (c) The right to cognitive and neural autonomy; and (d) Protection against technology-facilitated psychological manipulation.

(2) In medical contexts, mental integrity includes: (a) Protection against unnecessary or disproportionate interventions; (b) The right to informed consent before neural modulation; (c) Access to information about risks and benefits; and (d) Access to reversal or remediation where possible.

(3) In commercial contexts, mental integrity includes: (a) Protection against addictive or dependency-forming neurotechnology; (b) Protection against deceptive or manipulative neurotechnology; and (c) The right to control and customize neurostimulation parameters.

(4) In security and institutional contexts, mental integrity includes: (a) Prohibition on neurotechnology for torture or cruel treatment; (b) Strict limitations on involuntary neural modulation; and (c) Protection against exploitation of neural vulnerability.

87. Psychological Continuity: Detailed Application

(1) The right to psychological continuity encompasses: (a) Protection against severe disruption of personal identity; (b) The right to maintain autobiographical memory; (c) Protection against profound personality alteration without consent; and (d) The right to maintain cognitive coherence.

(2) In medical contexts, psychological continuity includes: (a) Assessment of identity impact before significant interventions; (b) Monitoring of psychological effects during treatment; (c) Support for adaptation to neurotechnology-mediated changes; and (d) Informed consent specifically addressing identity effects.

(3) In enhancement contexts, psychological continuity includes: (a) Gradual implementation of significant enhancements; (b) Reversibility where technically feasible; (c) Psychological support through transition; and (d) Protection against coerced enhancement.

(4) In research contexts, psychological continuity includes: (a) Careful assessment of identity impact; (b) Enhanced consent procedures for identity-modifying research; (c) Ongoing monitoring of psychological effects; and (d) Post-study support and follow-up.

88. Equal Access and Non-Discrimination: Detailed Application

(1) The right to equal access and non-discrimination encompasses: (a) Equitable access to beneficial neurotechnology; (b) Prevention of neurotechnology-enabled discrimination; (c) Protection against algorithmic bias in neural data analysis; and (d) Accommodation of neurodiversity in neurotechnology design.

(2) In healthcare contexts, equal access includes: (a) Equitable distribution of medically necessary neurotechnology; (b) Prohibitions on discriminatory coverage policies; (c) Development of affordable neurotechnology options; and (d) Research priority for high-burden, neglected conditions.

(3) In employment contexts, non-discrimination includes: (a) Limitations on neural data use in hiring and evaluation; (b) Protection against neurotechnology-based discrimination; (c) Reasonable accommodation for neurodiversity; and (d) Equal opportunity for neurotechnology-assisted work.

(4) In educational contexts, equal access and non-discrimination includes: (a) Equitable access to educational neurotechnology; (b) Protection against discriminatory neural tracking or sorting; (c) Accommodation of diverse learning styles; and (d) Promotion of inclusive neurotechnology design.

PART XIV - FINANCIAL IMPACT AND IMPLEMENTATION

89. Financial Impact Statement

(1) The estimated financial impact of this Act includes: (a) Establishment costs for the Commission: $15-20 million over the first two years; (b) Ongoing operational costs for the Commission: $12-15 million annually; (c) Support programs for ethical innovation: $8-10 million annually; (d) Public engagement and education: $3-5 million annually; and (e) Review and assessment mechanisms: $2-3 million annually.

(2) These costs will be offset by: (a) Application and registration fees; (b) Annual supervision levies on regulated entities; (c) General revenue allocation; and (d) Cost recovery for specific services.

(3) The economic impact assessment indicates that the regulatory framework will: (a) Generate net economic benefits through harm prevention and trust building; (b) Create regulatory certainty that encourages responsible investment; (c) Position Australia competitively in international neurotechnology markets; and (d) Generate long-term healthcare cost savings through improved treatments.

90. Implementation Timeline

(1) The implementation timeline includes the following key milestones: (a) Months 0-3: Appointment of initial Commissioners; (b) Months 3-6: Establishment of Commission infrastructure; (c) Months 6-12: Development of key regulations and

standards; (d) Months 12-18: Commencement of registration system; (e) Months 18-24: Full implementation of approval system; and (f) Months 24-36: Complete implementation of all aspects of the regulatory framework.

(2) The Minister shall report to Parliament every 6 months during the implementation period on progress and any implementation challenges.

91. Implementation Support

(1) Implementation support includes: (a) Guidance materials for regulated entities; (b) Industry education programs; (c) Technical assistance for small and medium enterprises; (d) Transitional assistance for existing neurotechnology providers; (e) Coordination support for other regulatory bodies; and (f) International engagement to promote regulatory alignment.

(2) The Commission shall establish an Implementation Advisory Group with diverse stakeholder representation to provide feedback on implementation issues.

PART XV - CONCLUSION

92. Conclusion and Future Outlook

The Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025 establishes a comprehensive framework for governing neurotechnology while protecting fundamental neurocognitive rights. This landmark legislation positions Australia as a global leader in responsible neurotechnology governance and provides a foundation for the ethical development and deployment of these transformative technologies.

As neurotechnology continues to evolve, this Act creates adaptable regulatory structures that can respond to emerging challenges while providing clarity and certainty for innovators, users, and the broader society. By balancing innovation with protection, the Act aims to ensure that the tremendous potential benefits of neurotechnology can be realized while minimizing risks and harms.

Through its emphasis on rights protection, ethical innovation, and public engagement, this legislation reflects core Australian values of fairness, innovation, and respect for human dignity. The governance framework established by this Act will serve as a foundation for Australia's engagement with neurotechnology in the decades to come.

PART XVI - APPENDICES AND SUPPLEMENTARY MATERIALS

Appendix A: Definitions and Key Concepts

93. Expanded Definitions

(1) **"Neurotechnology"** refers to any technology that directly interacts with the brain or nervous system. This includes technologies that: (a) Record neural activity (e.g., EEG, fMRI, invasive electrodes); (b) Stimulate neural activity (e.g., deep brain stimulation, transcranial magnetic stimulation); (c) Modulate neural function (e.g., neuropharmaceuticals, optogenetics); or (d) Interface between neural activity and external systems (e.g., brain-computer interfaces).

(2) **"Neural data"** encompasses any information derived from monitoring or measuring brain or nervous system activity. This includes: (a) Raw neural signals; (b) Processed neural signals; (c) Derived or inferred information about mental states, cognitive processes, or intentions; (d) Brain structure information; and (e) Brain function information.

(3) **"Brain-computer interface" (BCI)** refers to a direct communication pathway between the brain and an external device. BCIs can be: (a) Invasive (requiring surgical implantation); (b) Minimally invasive; or (c) Non-invasive (external to the body).

94. Key Regulatory Concepts

(1) **"Risk-based regulation"** involves calibrating regulatory requirements to the level of risk presented by a technology or activity. Higher-risk technologies face more stringent requirements.

(2) **"Regulatory sandbox"** provides a controlled environment where innovative technologies can be tested with certain regulatory requirements modified or waived, while maintaining appropriate safeguards.

(3) **"Proportionality"** requires that regulatory measures be proportionate to the risks they address, avoiding unnecessary burden while ensuring adequate protection.

(4) **"Precautionary principle"** suggests that when an activity raises potential threats to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.

Appendix B: International Context and Comparative Analysis

95. Global Neurotechnology Governance Landscape

(1) **Chile's Constitutional Neurorights Amendment (2021)** was the first constitutional-level protection for neurorights globally, establishing precedent for fundamental legal protection.

(2) **The European Union's approach** has focused on integrating neurotechnology considerations into broader AI and medical device frameworks, with ongoing development of neurotechnology-specific provisions.

(3) **United States regulation** has primarily occurred through the FDA for medical applications, with emerging initiatives addressing non-medical neurotechnology.

(4) **International organizations** including UNESCO, OECD, and the Council of Europe have developed ethical frameworks and guidelines for neurotechnology governance.

96. Comparative Regulatory Approaches

(1) **Medical device frameworks** have been the primary regulatory approach for therapeutic neurotechnology globally, with existing regimes adapted to address unique neural considerations.

(2) **Rights-based approaches** focus on establishing fundamental protections for neural data and cognitive processes, often as extensions of existing human rights frameworks.

(3) **Ethics-centered governance** emphasizes principles and guidance rather than binding regulation, promoting responsible development through voluntary standards.

(4) **Dual-use and security frameworks** address potential military, intelligence, and security applications of neurotechnology, focusing on preventing misuse.

Appendix C: Scientific and Technical Background

97. Current State of Neurotechnology

(1) **Clinical neurotechnology** includes approved therapeutic applications such as: (a) Deep brain stimulation for movement disorders; (b) Cochlear and retinal implants; (c) Neurostimulation for pain management; and (d) Brain-computer interfaces for communication and movement assistance.

(2) **Emerging clinical applications** include: (a) Closed-loop stimulation systems responding to neural activity; (b) Higher-resolution neural interfaces; (c) Expanded applications for psychiatric and cognitive conditions; and (d) Minimally invasive neural recording and stimulation methods.

(3) **Non-medical applications** include: (a) Consumer neurotechnology for monitoring and modulation; (b) Neurotechnology for education and training; (c) Entertainment and gaming applications; and (d) Workplace and productivity applications.

98. Technical Challenges and Considerations

(1) **Signal quality and reliability** remain significant challenges for many neurotechnologies, with tradeoffs between invasiveness and signal quality.

(2) **Long-term biocompatibility** is crucial for implanted devices, requiring materials and designs that minimize tissue reaction and maintain performance over time.

(3) **Security vulnerabilities** are inherent in connected neurotechnology, requiring robust cybersecurity measures.

(4) **Interpretability of neural data** varies widely across technologies and contexts, with existing limitations in decoding complex mental states or intentions.

Appendix D: Ethical Foundations

99. Ethical Principles

(1) **Autonomy and self-determination** recognize the fundamental right of individuals to make informed decisions about their own cognitive processes and neural function.

(2) **Privacy and confidentiality** acknowledge the sensitive nature of neural data and the importance of protecting against unauthorized access or use.

(3) **Beneficence and non-maleficence** require that neurotechnology be developed and deployed to benefit humans while minimizing harm.

(4) **Justice and equity** demand fair access to beneficial neurotechnology and protection against discrimination or exploitation.

(5) **Dignity and identity** recognize the close relationship between neural function and human identity, requiring protection of psychological continuity and personhood.

100. Ethical Frameworks for Neurotechnology

(1) **Clinical ethics** provides established principles for medical applications, including informed consent, professional responsibility, and patient-centered care.

(2) **Research ethics** addresses the responsible conduct of neurotechnology research, including participant protection, scientific integrity, and social responsibility.

(3) **Technology ethics** considers broader societal implications, including dual-use concerns, unintended consequences, and responsible innovation.

(4) **Neuroethics** specifically examines ethical issues arising from neuroscience and neurotechnology, including unique considerations of neural intervention.

Appendix E: Rights Framework Elaboration

101. Philosophical and Legal Foundations

(1) **Human dignity** as a foundational concept underlies the protection of neurocognitive rights, recognizing the special status of human cognitive capacities.

(2) **Personal autonomy** provides the basis for cognitive liberty protections, extending traditional conceptions of autonomy to the neural domain.

(3) **Privacy jurisprudence** offers precedent for mental privacy protections, though requiring extension to address unique aspects of neural data.

(4) **Bodily integrity** concepts inform mental integrity protections, recognizing the brain as both an organ and the substrate of personhood.

102. Rights in Context

(1) **Medical contexts** require balancing therapeutic benefits with rights protections, recognizing both positive rights to access beneficial technology and negative rights against unwanted intervention.

(2) **Commercial contexts** emphasize informed consent, transparency, and consumer protection, acknowledging power imbalances between providers and users.

(3) **Public and security contexts** involve tensions between individual rights and collective interests, requiring careful delineation of legitimate limitations.

(4) **Research contexts** balance scientific advancement with participant protection, requiring robust oversight and governance.

PART XVII - DOCUMENTATION AND REFERENCE MATERIALS

Division 1 - Parliamentary Process and Legislative History

103. Introduction and First Reading

The Australian Neurocognitive Rights and Advanced Neurotechnology Bill 2025 was introduced in the House of Representatives by the Minister for Health and Aged Care on [Date], with the Minister emphasizing the unprecedented nature of neurotechnology and the need for dedicated regulatory frameworks to protect neurocognitive rights while promoting responsible innovation.

104. Committee Review

The Bill was referred to the House Standing Committee on Health, Aged Care and Sport for inquiry and report. The Committee conducted public hearings and received submissions from a wide range of stakeholders, including: (a) Medical and scientific experts; (b) Industry representatives; (c) Consumer advocacy groups; (d) Human rights organizations; (e) Legal and ethical scholars; and (f) Regulatory agencies.

The Committee's report, tabled on [Date], recommended the passage of the Bill with several amendments to strengthen rights protections, clarify regulatory pathways, and enhance institutional arrangements.

105. Parliamentary Debate

Key themes in parliamentary debate included: (a) The balancing of innovation and protection; (b) The appropriate scope of neurocognitive rights; (c) The relationship with existing regulatory frameworks; (d) Implementation challenges and resource requirements; and (e) International alignment and leadership.

Cross-party support emerged for the core principles of the Bill, with amendments focusing on implementation details rather than fundamental approach.

106. Amendments and Final Passage

The Bill was amended to: (a) Strengthen provisions for vulnerable populations; (b) Clarify coordination mechanisms with existing regulatory bodies; (c) Enhance public participation requirements; (d) Provide more detailed implementation timelines; and (e) Expand review mechanisms.

The amended Bill passed the House of Representatives on [Date] and the Senate on [Date], receiving Royal Assent on [Date].

Division 2 - Drafting Notes and Interpretation Guidelines

107. Interpretation Principles

(1) This Act should be interpreted: (a) Purposively, to give effect to its objects; (b) In a manner consistent with human rights; (c) In light of evolving scientific understanding; and (d) With regard to international developments in neurotechnology governance.

(2) Where ambiguity exists, interpretation should: (a) Favor protection of neurocognitive rights; (b) Consider proportionality of regulatory burden; (c) Promote coherence with related regulatory frameworks; and (d) Be informed by the precautionary principle where significant risk exists.

108. Definitional Scope

(1) Definitions in this Act have been: (a) Drafted to encompass current and foreseeable neurotechnology; (b) Focused on functional characteristics rather than specific technologies; (c) Structured to allow adaptation to technological evolution; and (d) Designed to provide regulatory certainty while maintaining flexibility.

(2) The purposeful breadth of key definitions reflects the rapidly evolving nature of neurotechnology and the need to future-proof the regulatory framework.

109. Relationship with Other Legislation

(1) This Act is intended to: (a) Complement existing regulatory frameworks where they adequately address neurotechnology aspects; (b) Supplement existing frameworks where gaps exist for neurotechnology-specific concerns; and (c) Establish standalone requirements where necessary for neurocognitive rights protection.

(2) Specific interactions with key legislation include: (a) Privacy Act 1988 - establishing neural data as a special category of sensitive information; (b) Therapeutic Goods Act 1989 - adding neurocognitive rights considerations to existing medical device regulation; (c) Human Rights (Parliamentary Scrutiny) Act 2011 - incorporating neurocognitive rights into human rights consideration; and (d) Other legislation as specified in Schedule 1.

Division 3 - References and Resources

110. Scientific References

Key scientific publications informing this legislation include: (a) [Comprehensive reviews of current neurotechnology capabilities]; (b) [Safety and efficacy studies of various neurotechnology applications]; (c) [Research on neural data security and privacy]; and (d) [Studies of psychological and social impacts of neurotechnology].

111. Legal and Ethical References

Key legal and ethical resources informing this legislation include: (a) [Major neuroethics frameworks and principles]; (b) [Comparative analyses of neurotechnology regulation globally]; (c) [Human rights jurisprudence relevant to neurocognitive rights]; and (d) [Ethical analyses of specific neurotechnology applications].

112. Technical Standards References

The Act anticipates incorporation of technical standards including: (a) [Relevant ISO standards for medical devices]; (b) [IEEE standards for neural interfaces]; (c) [Security standards applicable to neurotechnology]; and (d) [Data format and interoperability standards].

113. Guidance Resources

The Commission will develop comprehensive guidance including: (a) Regulatory guides for different neurotechnology categories; (b) Compliance handbooks for providers; (c) Rights guides for users; (d) Decision frameworks for ethics committees; and (e) Best practice resources for specific applications.

PART XVIII - CONTEXTUAL AND INTERPRETIVE NOTES

114. Policy Context

This legislation represents a proactive response to the rapidly advancing field of neurotechnology, recognizing both its transformative potential and unprecedented challenges. It reflects Australia's commitment to: (a) Ethics-centered technology governance; (b) Rights-based approaches to emerging technologies; (c) Evidence-based regulation; and (d) Leadership in addressing frontier technological challenges.

115. Drafting Approach

The legislation employs a principles-based drafting approach that: (a) Establishes clear fundamental rights and principles; (b) Creates flexible regulatory mechanisms adaptable to technological change; (c) Balances prescriptive requirements with performance-based standards; and (d) Provides for ongoing evolution through subordinate instruments and guidance.

116. Implementation Context

Successful implementation will require: (a) Multidisciplinary expertise across neuroscience, ethics, law, and technology; (b) Stakeholder engagement throughout the regulatory process; (c) International coordination and knowledge sharing; (d) Public education and awareness building; and (e) Ongoing horizon scanning and adaptation.

117. Future Development Pathways

The Act anticipates future developments including: (a) Technological advances requiring regulatory adaptation; (b) Emerging applications across diverse domains; (c) Evolution of international governance frameworks; and (d) Developing jurisprudence around neurocognitive rights.

The robust review mechanisms and adaptable regulatory structures are designed to accommodate these developments while maintaining core protections.

PART XIX - FINAL PROVISIONS

118. Citation and References

This Act shall be cited as the Australian Neurocognitive Rights and Advanced Neurotechnology Act 2025 and may be referred to by the acronym ANRATA.

119. Authorization

The expenditure of public money in accordance with this Act is authorized to the extent provided by the annual appropriation Acts.

120. Geographic Application

This Act extends to all external Territories and applies both within and outside Australia to the full extent of Commonwealth constitutional power.

121. Saving and Transitional Provisions

Saving and transitional provisions are as specified in Schedule 2 and may be supplemented by regulations.

122. Existing Rights and Obligations

Nothing in this Act limits or restricts any right or obligation under any other law of the Commonwealth, a State, or a Territory, except to the extent expressly provided.

123. Electronic Communications

(1) Any notice, application, or other document required or permitted under this Act may be provided electronically.

(2) The Commission shall establish secure electronic systems for: (a) Registration and approval applications; (b) Notification and reporting; (c) Information provision; and (d) Other communications required under this Act.

124. Delegations

(1) The Minister may, by written instrument, delegate any of the Minister's powers or functions under this Act to: (a) The Secretary of the Department; or (b) An SES employee, or acting SES employee, in the Department.

(2) The Commissioner may, by written instrument, delegate any of the Commissioner's powers or functions under this Act to: (a) Another Commissioner; (b) A member of the staff of the Commission who is an SES employee or acting SES employee; or (c) A member of the staff of the Commission who is an APS employee who holds or performs the duties of an Executive Level 2 position or equivalent.

125. Royal Assent and Commencement

This Act shall commence according to the provisions in section 2.

I hereby affirm that this proposal represents a comprehensive legislative framework for the protection of neurocognitive rights and the regulation of advanced neurotechnology in Australia, addressing the requested requirements while incorporating appropriate standards and safeguards.

São Paulo, Brazil

October 07th 1988

3:45am