Issues Paper

Neurotechnology
law and the legal profession

with Dr Allan McCay

Advances in Neurotechnology and the Law - Anticipating the challenges and opportunities

01 December 2022



Oficial Event Host Baker McKenzie.

Facilitated and produced by JEWELROCK THE PINNACLE OF EVENT EXPERIENCES

On Thursday 01 December, Jewelrock hosted a panel of influential national and internationally acclaimed thought leaders and luminaries to discuss Dr Allan McCay's report *Neurotechnology, law and the legal profession* at an elegant networking breakfast forum held at Baker McKenzie's executive Sydney offices.

A curated guest list focussed on bringing together the technology, legal, government and academic communities for an interactive robust debate and intellectual discussion to broach the topic of the protection of neurorights together with many other legal issues - and deliver a strong indication of the need for a deeper understanding and conversation around a legal framework.

Why did Jewelrock think the time was right for this forum?

In August of this year Dr McCay published the world's first substantial overview of neurotechnology and its implications for the law and the legal profession.

Commissioned by The Law Society of England and Wales, the paper called for urgent consideration of how the new tech will be regulated.

The development and use of neurotechnologies are fraught with ethical, privacy and security concerns. Following this, it could have a substantial impact on law and the legal profession making it more and more imperative to understand how the law should respond to this progress.

In addition, with the UNHRC Resolution on neurotechnology passed on 06 October and developments from both Australian and overseas companies -this Australian Neurotech Forum was timely.

Jewelrock leveraged this forum to create a community of stakeholders, and to build momentum for the imperative discussion between the neurotech and legal communities with a plan to host a follow-on forum in early 2023. The next forum will expand the discussion to consider neuorotech in the broader context of other developments in data, AI and the metaverse.

This Issues Paper delivers the relevance and need for the continuity of the discussion of neurotech and is an important document to help shape consideration and guidance for law reform, human rights and other relevant bodies in Australia. It is to be hoped that a process has been started that will lead legal change aimed at proactively channeling this emerging technology in order to maximise the considerable upside whilst minimizing the downsides.

Andra

Andra Müller
Founder and Director, Jewelrock

Overview

Speakers and Panellists



Dr Allan McCay
Academic Fellow, Sydney Law School
Deputy Director, Sydney Institute of Criminology
Author of the Law Society of England and Wales report
Neurotechnology, law and the legal profession (August 2022)



Jared Genser
International human rights lawyer
General Counsel, Neurorights Foundation
Managing Director of Perseus Strategies, LLC
Adjunct Professor of Law at
Georgetown University Law Center



Emeritus Professor Rosalind Croucher AM
President of the Australian Human Rights Commission
Former President of the Australian Law Reform Commission



Professor Nicholas Opie
Co-founder and CTO of Synchron



Panel Moderator
Andrew Birmingham



Emeritus Professor Jeffrey Rosenfeld AC, OBE
Internationally recognised neurosurgeon and
one of Australia's leading academic neurosurgeons



Natalie Bryce
Global Sector Lead, Healthcare
Herbert Smith Freehills



Issues Paper written by
Brad Howarth



Associate Professor Frederic Gilbert
Philosopher pioneering the ethics of invasive
brain-computer interfaces, University of Tasmania



Adrian Lawrence
Partner in Baker McKenzie's IPTech Group
and Australian Offices Chair



Introduction

The human brain has traditionally been one of the last great frontiers of scientific exploration, but in recent years scientists have taken tremendous strides towards unravelling its mysteries.

There have been many exciting breakthroughs in the field of neurotechnology, which is the term used to describe methods and instruments that enable a direct connection between devices and the nervous system. Foremost among these instruments are neurotechnology devices, including so-called brain computer interface (BCI) devices which can interpret the brain's signals, down to the resolution of individual thoughts.

Numerous examples of neurotechnological devices being used for medical purposes can be found today, such as Cochlear hearing implants and the deep brain stimulating electrodes used in the treatment of Parkinson's Disease.

However, new developments are pushing the boundaries of possibility, including devices that can read individual thoughts to produce simulated speech or robotic action, as well as longer-term projects to restore sight to the blind.

These still represent only the beginning of what's possible. But aside from the obvious benefits, neurotechnology also has the potential to be employed for nefarious purposes, such as extracting private information, inflicting pain, or controlling actions.

> In short, neurotechnology has placed us on the cusp of being able to not only read people's thoughts, but to possibly also control their actions.

While much of the research in neurotechnology has occurred in the medical sector, its potential as the foundation for a new generation of consumer devices is quickly becoming clear. Neurotechnology is already big business, with Expert Market Research estimating the global neurotechnology market will grow in value from US$10.7 billion in 2020 to US$21 billion by 2026. [1]

Inevitably, the speed of breakthroughs in neurotechnology threatens to outpace our ability to comprehend and safely accommodate them within society. Each new development raises significant ethical, moral, and legal challenges, and we face the very real risk that capabilities for interpreting and controlling brain signals will become widely available before their consequences are understood – and before safeguards can be put in place to ensure they are used appropriately.

These topics and more provided the basis for a discussion involving many of Australia's foremost experts on neuroscience and the law, orchestrated by Jewelrock at the Sydney offices of the law firm Baker McKenzie in December 2022. As the first gathering of its kind in Australia, the forum enabled participants from different backgrounds and disciplines to share knowledge and find common alignment that could lead to further discussion and collaboration.

Much of the discussion was framed by topics described by Sydney Law School academic Dr Allan McCay in his world-first report on the impacts of neurotechnology on law and the legal profession, published in August 2022 by The Law Society of England and Wales and titled ***Neurotechnology, law and the legal profession.***[2]

[1] *www.expertmarketresearch.com/reports/neurotechnology-market*

[2] *www.lawsociety.org.uk/topics/research/how-will-brain-monitoring-technology-influence-the-practice-of-law*

Neurotechnology and human rights

The session commenced with a discussion with Jared Genser, an international human rights lawyer and managing director of the law firm Perseus Strategies LLC, whose clients have included former Czech Republic President Václav Havel and Nobel Peace Prize Laureates Desmond Tutu, Liu Xiaobo, and Elie Wiesel.

Genser described how his interest in neurotechnology was first sparked through a conversation with Columbia University neurotechnology expert Professor Rafael Yuste.

"My overall sense was that nobody in the world of international human rights really had any idea of what's coming in neurotech," ***Genser said.***

Prof Yuste however had been thinking about these considerations in consultation with associates at Columbia University, and had defined five 'neurorights' relating to rights to mental identity, mental agency and free will, mental privacy, fair access to mental augmentation, and the right to protection from algorithmic bias when neurotechnology was combined with artificial intelligence.

Genser and Prof Yuste have since created the non-profit Neurorights Foundation, whose aim is to promote innovation in the field while also considering the ethical and moral dimensions of neurotechnology to ensure fundamental human rights are protected.

Advances in neurotechnology are coming quickly, with Genser describing an example from 2021 of a person who was paralysed and non-verbal but who was able to use an implanted neurotechnology device to communicate at a rate of 18 words per minute at up to 94 per cent accuracy.

By Genser's estimate, non-invasive versions of this technology could be available as wearable devices in as little as three to five years.

"You would be able to do word processing by thinking of the words and having them appear on your screen," ***Genser said.*** *"That is a great thing in terms of productivity. But now image that same device being placed on the head of a political dissident being interrogated."*

With the brain being the seat of all human memory, perception, and personality, Genser said the potential for these technologies to be used to perpetrate human rights violations was enormous, as they challenged not only the privacy of our minds but also our sense of self and free will.

"The rise of consumer neurotechnology emphasises the need for laws and regulations that reflect how the technology is advancing," ***Genser said.*** *"BCIs that do not require implantation in the brain are already marketed as consumer products with claims that they support meditation and wellness, improve learning efficiency, and enhance brain health. But unlike implanted devices, which are regulated as medical devices, wellness devices are consumer devices and are subject to minimal or no regulation."*



Hence people using these devices might be potentially endangering their health while forgoing essential protections, such as having a full understanding of their possible consequences.

"If you were to describe some of the things that are already possible in neurotechnology today, people would be shocked," ***Genser said.*** *"Public education and awareness raising is going to be very, very important here, because people around the world that might benefit from these products are also going to want to have their human rights and privacy appropriately respected."*

However, Genser also suggested that in many instances existing laws could be adequate for regulating neurotechnology. For instance, a neurotechnological device that could inflict pain on a person would already be prohibited under the United Nations' Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. But in other instances, such as when thoughts were read but not acted upon, a person's rights were less clear.

"Effective multilateral cooperation, national action, industry engagement, and citizen education are really all necessary to advance the adoption of neurorights and to close the protection gaps under international human rights law," ***Genser said.*** *"This can help guide neurotechnology's ethical development and reveal the strongest paths to preventing the technology from being misused and abused."*

Breaking down the barriers of neurotechnology

One of the key areas of advancement for neurotechnology has been improvements in the accuracy with which brain signals are interpreted, such that it is now possible to read individual thoughts and use brain signals to control external devices.

The resolution at which signals can be sent and received depends greatly on the proximity of the sensing devices to the nerve cells they are communicating with.

Several methods are employed today for the placement of electrodes: outside of the skull; under the scalp; under the bone; near to (extra-dural) or directly in contact with the surface of the brain (sub-dural); non-invasively into the large veins beneath the skull (Synchron-Stentrode); or implanted directly into the cortex of the brain. While the latter technique has demonstrated the highest fidelity, the need for surgical implantation and the corresponding legal considerations have limited its deployment. Devices that place electrodes outside of the skull have been shown to be less effective, but also avoid many regulatory restrictions.

The internationally recognised Australian neurosurgeon Professor Jeffrey Rosenfeld AC OBE has played a key role in the development of implanted neurotechnologies through his work on bionic vision at Monash University and related organisations. Prof Rosenfeld cautioned that despite their advantages, implanted devices carried significant ethical challenges, many of which related to the responsibilities of the individuals and organisations that carried out the implantations and managed the devices.

"The immediate issue is whether people are given a true picture of the entire aspect of the device that is being put into their head and are giving informed consent," ***Rosenfeld said.***

One example of risk related to the longevity of the devices and their need for ongoing maintenance or upgrading. Prof Rosenfeld raised the very question of who takes responsibility for a device when the company that implanted it goes bankrupt, as happened with the bionic eye company Second Sight.

He suggested the ethical challenges of neurotechnology also extended to consumer-grade devices, whose potential for harm demanded tighter regulation.

"As soon as you get into the non-invasive area of brain computer interface, you get into the non-regulated area where anything goes, and that is where things need to be tightened," ***he said.***

According to Natalie Bryce, global sector lead for healthcare at the law firm Herbert Smith Freehills, digital healthcare, including neurotechnology, blurred the boundaries between devices and services.

"Any time you have a product that captures data and then automates a clinical response, you may be replacing the decision of a healthcare professional with the output of a commercial product," ***she said.*** *"It may actually be a better clinical intervention – faster and more targeted. But it is replacing a relationship where the decision-maker has professional and ethical obligations to the patient with a consumer interaction where virtually anything is up for grabs – provided it has been properly disclosed and consented to – and this represents a challenge to traditional sources of protection for patients".*

Bryce said the absence of the 'no harm' principle was particularly acute when considering secondary use of the kinds of information which neurotechnology products could potentially collect.

"Even if you could construct a cast-iron consent to secondary uses of information about, say, vulnerability to suggestion, a healthcare professional wouldn't sell that information because of ethical constraints," ***she said.*** *"The line between something that is a consumer good and healthcare is a really ricky one. Is it healthcare because of what it does, or because of the information it collects?"*

"If the manufacturer says the product can't be used for medical purposes, but it is foreseeable that consumers will do just that, should it be regulated as a medical device or a consumer product?"

Bryce said these considerations were made more complex by the siloed nature of the healthcare system, where services, goods, and data were regulated separately. Challenges would grow as all three areas merged within digital health products, including neurotechnology-based service providers.

Biomedical engineer and world expert in neural interfaces Prof Nicholas Opie has direct experience with these questions through his work as the co-founder and chief technology officer of Synchron, a company spun out of the University of Melbourne which is now regarded as a global leader in the creation of neurotechnologies that can enable people with paralysis to control external equipment.

This work had led him to begin considering how neurotechnology professionals and the legal professionals might work together to define the boundaries of regulation, especially in relation to the lines between consumer-grade 'toys' and regulated medical devices and services.

"It is right that we start discussing this and coming up with some sort of framework on how far down the track a 'toy' can go before it is a medical product and how can we regulate that," ***Opie said.***

This led the conversation back to the topic of consent, with Prof Rosenfeld questioning whether citizens were truly capable of giving informed consent for the use of even non-invasive neurotechnologies.

"It is easy to see how the process could get corrupted by unscrupulous practitioners that want to see their device become a commercial success," ***Rosenfeld said.*** *"It is very important that the process remains strictly controlled."*





Neurotechnology and the law

When the Law Society of England and Wales asked Dr Allan McCay to examine the implications of neurotechnology, it gave him with the opportunity to examine the various areas of impact from multiple perspectives, from human rights considerations to the adequacy of existing systems of regulations, all the way through to how neurotechnology might impact the practice of law itself.

One of the concerns he identified was the potential for neurotechnology to be used for unconscionable conduct or to influence behaviour.

This is an area of particular concern for associate Professor Frederic Gilbert, an ethicist who has spent the past decade examining the potential effects of implanted neurotechnologies and the subjective experience of the users. He said that while existing neurotechnologies often showed great effectiveness when treating specific conditions, research also uncovered side effects such as induced depression, personality changes, and psychological rejection.

"What we can clearly observe is even if the technology is effective, we cannot automatically derive the conclusion that it will lead to an improvement of the quality of life for the patient," ***Gilbert said.***

According to Adrian Lawrence, chair of Baker McKenzie's Australian offices, and a partner in the IPTech Group, findings such as these raised the urgency of the need to ensure their use was properly regulated.

"When we see a new technology, we always have to ask ourselves the questions of how our existing regulation applies to that technology and how might we need to enhance that existing regulation, or whether we are in a situation where something so new is happening that we need to radically change the way we regulate that issue or introduce some new area of regulation entirely," ***Lawrence said.***

For example, when considering the collection of data from neurotechnology devices, Lawrence said it was important to first consider whether existing data privacy regulation might be applicable, and whether consent provisions could be transferred into this new realm.

"Do we need to move to a new paradigm where we say consent might not be enough?" ***Lawrence asked.*** *"We certainly want consent to be freely given, and we want it to be fully informed, but perhaps we need to impose limits to its use as well."*

A key element of this challenge is the gaps between the standards applied for medical devices and those for consumers devices, where the tests of informed consent are significantly different.

"Even if you can convince your patient, or user, or wearer, that the use of data is something they should say yes to, maybe we would still say there should be limits to that use, and go down a path that is perhaps specific to neuro-data, to say that that data set needs to be more regulated," ***Lawrence said.***

According to the President of the Australian Human Rights Commission Emeritus Professor Rosalind Croucher AM, there were parallels between the situation facing the law today and many situations that have preceded it. She quoted a statement from former High Court Justice Windeyer who when discussing the issue of nervous shock noted, 'the law can be found marching with [new discoveries in science and medicine] but in the rear and limping a little.'

"The same thing can be applied with any new development in science and medicine, that law limps behind," ***Prof Croucher said.*** *"And that goes to how we develop doctrines in law that respond to the current situations in medicine and in science that challenge us to think through other lenses. When you add in the lens of human rights, you drag in lots of different ideas as well."*

Prof Croucher said that law, human rights, and medicine were all allied in conversations relating to these new challenges, and the ability to extend these conversations to additional disciplines such as engineering would be critical to their resolution.

"Then in our various fields we can unpack them," ***she said.*** *"It is just about refining the tools we have to accommodate new situations."*

Prof Croucher said this work would be essential if the law was to stay abreast of not only the challenges that can be foreseen today, but also those that are unforeseen.

According to Dr McCay, the neurotechnology community already held significant concerns that new technologies developed with the best of intentions could be co-opted for nefarious purposes. He identified some governments that had already recognised and responded to this possibility, such as the Chilean government's 2021 amendments to their country's constitution[3] and its Neuroprotection Bill, which was currently moving through their legislative process.

"With neurotechnology, it is not known how it is going to take off, so there is a balance between waiting until we know what the problems are or trying to guess them from the armchair and acting," ***Dr McCay said.*** *"Scholars and maybe the legal profession have got to think about it now, with a view that once things do start to develop, they are ready to take action."*

Bryce said this need for law to act now was also driven by the lessons of previous incidences where new concepts and technologies were embraced by the public before they were properly regulated.

"It is very difficult to put the genie back in the bottle," ***Bryce said.*** *"It is important to think about possible misuse and complications and sources of risk, rather than allowing a product that later proves to be dangerous to become something that people rely on and have integrated into their lives."*

Prof Rosenfeld suggested it was easy to imagine unacceptable outcomes from the use of neurotechnologies, such as private neuro-data being collected and used for commercial purposes without proper consent, being used to coerce action, or even the possibility for these devices being used to block people from taking actions.

"These are all unacceptable outcomes that require some thinking about now in terms of the legal framework around controlling these devices," ***Rosenfeld said.***

[3] *link.springer.com/article/10.1007/s00146-022-01396-0*

It starts with thought

Ultimately, neurotechnology speaks to the idea of stimulating or accessing the mind, and as shown through this discussion, that stimulation or access can take place long before any neurotechnological legal frameworks are applied.

As Dr McCay suggested, while significant challenges remained, simply having conversations such as these was an important step forward for raising awareness of current and future issues and preparing appropriate responses, and for encouraging researchers and commercial developers to steer their activities away from contentious outcomes.

"Even if the law has to lag behind, the threat of it can play a positive role in prompting reflection within companies about what they should do," ***McCay said.***

Hence Prof Rosenfeld said it was important to maintain a constant dialogue between the people introducing and developing the technology and the lawyers and ethicists who are striving to govern its use.

"You need to start thinking about this now, which is what we are doing here today," ***Rosenfeld said.*** *"Is important that the various disciplines continue to meet and discuss these things, because that is the way the law will keep up."*

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