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# Chilean neurorights legislation and its relevance for mental health: Criticisms and outlook

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## ABSTRACT

**Background.** Recently, the academic world has established a series of reconfigurations of emerging human rights, in order to safeguard the mental integrity of people exposed to neurotechnologies. The recommendations of different stakeholders and a literature review support regulation of these technologies. There are different proposals for regulation, some in soft law and others in objective law. The type of regulation chosen can have repercussions on clinical practice, research, and public policy. The constitutional enactment of neurorights in Chile has been criticized in the academic fields of neuroethics and law as having potential negative effects on mental health research. **Objective.** To analyze in light of the available literature whether the construction of neurorights could create ethical conflicts in the field of mental health, or if it could offer protection against the disruptive use of various neurotechnologies. **Method.** This analysis included a narrative review of studies included in the PsycInfo, Springer, JSTOR, Medline, Scopus, PubMed, CINALH, and Web of Science databases, without restrictions on language or year of publication. **Results.** The enactment of neurorights as hard law is found not to be detrimental to the field of mental health. **Discussion and conclusion.** This article argues that the regulation of neurorights does not threaten the framework of an ecosystem that uses neurotechnologies. On the contrary, such regulation offers protections to people within the complex system of neurotechnologies.

**Keywords:** Neurorights, neuroethics, neurotechnologies, regulations, mental health.

## RESUMEN

**Antecedentes.** Recientemente, el mundo académico ha establecido una serie de reconfiguraciones de derechos humanos emergentes, con el fin de salvaguardar la indemnidad mental de las personas expuestas a las neurotecnologías. Las recomendaciones de las diferentes partes interesadas y de una revisión bibliográfica son la regulación de estas. Existen diferentes ejemplos de regulación, algunos de derecho blando y otros de derecho objetivo. El tipo de regulación puede tener repercusiones en la práctica clínica, la investigación y las políticas públicas de una comunidad. La consagración constitucional chilena de los neuroderechos ha sido criticada desde el mundo académico de la neuroética y también desde el derecho argumentándose que podría ser negativa para la investigación en salud mental. **Objetivo.** Analizar a la luz de la literatura disponible si la constitucionalización de los neuroderechos es éticamente conflictiva en el campo de la salud mental o más bien la protege frente del uso disruptivo de diversas neurotecnologías. **Método.** Revisión narrativa de estudios incluidos en las siguientes bases de datos (PsycInfo, Springer, JSTOR, Medline, Scopus, PubMed, CINALH y Web of Science) sin restricciones de idioma o año de publicación. **Resultados.** No se considera que la consagración de los neuroderechos como hard law sea perjudicial en el ámbito de la salud mental. **Discusión y conclusión.** Se discute si los neuroderechos son una regulación amenazante en el marco de un ecosistema que utiliza neurotecnologías. Se concluye que, a pesar de las críticas, no lo es, sino que favorece la protección de las personas del uso inapropiado de neurotecnologías.

**Palabras clave:** Neuroderechos, neuroética, neurotecnologías, regulaciones, salud mental.

## INTRODUCTION

Neurorights are a recent and evolving legal construct. They are emerging human rights, reconfigured in response to the impact of neurotechnology, especially its disruptive use on people (Ienca, 2021; Cornejo Plaza, 2021a). The concept has its origin in two foundational texts in ethics, neuroscience, and law, one by Marcello Ienca and Roberto Andorno (2017) and the other by the research group led by Rafael Yuste et al. (2017).

Although there is a consensus favoring the regulation of neurotechnologies (OECD, 2019; Goering, 2021), there is controversy over the choice of legal methods to carry out that regulation and the possible effects of these methods. One possibility is to regulate the use of neurotechnologies through "soft law," which favors the flexibility of regulations in the face of the vertiginous advance and obsolescence of technology (Marchant, 2011). Another solution is "hard law," which has been adopted by Chile. It is important to note that the concept of neurorights has been controversial among scholars. This article thus seeks to respond to a series of observations from the world of neuroethics and law, which warn that the Chilean regulation should not be replicated in other countries because it could have a negative impact on research and mental health.

In what follows we will analyze the concept of neurorights and address the main criticisms of the Chilean approach. Our conclusion is that given the disruptive use of neurotechnologies, the Chilean regulation has a positive effect; it does not hinder but rather protects the field of mental health.

## METHOD

This study consisted of a narrative review of the main critiques of the concept of neurorights in the PsycInfo, Springer, JSTOR, Medline, Scopus, PubMed, CINALH, and Web of Science databases, with no restrictions on language or year of publication. An analysis is presented of the major criticisms, followed by a review of biomedical legislation and Chilean mental health law, in light of those criticisms.

### What are neurorights?

Neurorights are a reconfiguration of rights that are especially affected by neurotechnology, artificial intelligence, and the metaverse (Genser, Herrmann, & Yuste, 2022). In 2017, two publications introduced the topic to academic discussion. In "Four Ethical Priorities for Neurotechnologies and AI," Yuste et al. (2017) propose a new set of human rights in response to the advance of neurotechnology: the rights to mental privacy, identity and personal autonomy, free will and self-determination, and protection from bias in algorithms or automated decision-making processes. In "Towards New Human Rights in the Age of Neuroscience and Neurotechnology," Ienca and Andorno (2017) address four neurorights: cognitive freedom, mental privacy, mental integrity, and psychological continuity.

Both papers agree on the importance of regulatory consensus on neurorights. One such right would be the right to enhancement neurotechnology, which would allow people to radically extend their resilience and capacities. "The pressure to adopt enhancing neurotechnologies, such as those that allow people to radically expand their endurance or sensory or mental capacities, is likely to change societal norms, raise issues of equitable access, and generate new forms of discrimination" (Yuste et al., 2017, p. 163). However, only Yuste et al. (2021) goes so far as to define this neuroright, in addition to the neuroright to decision-making free of algorithmic biases (Cornejo Plaza, 2021a). These are two of the most controversial neurorights (Muñoz, 2019; Borbón & Borbón, 2021).

### Major criticisms of neurorights

Chile recently passed Law No. 21.383, modifying the final clause of Article 19, Number 1 of the Constitution, regarding the protection of mental integrity in relation to the advance of neurotechnologies. In addition, a regulation of neurotechnologies bill, which deals with the protection of neurorights, is currently under consideration; it would regulate research and development of neurotechnologies.[1]

The introduction of this legislation was met with criticism from Chilean academics (Zuñiga-Fajuri et al., 2021; Ruiz et al., 2021; López-Silva & Madrid, 2021) and civil society. One line of criticism argued that these rights are already protected by the Constitution and international treaties to which Chile is a signatory. The Constitution already guarantees the rights to privacy, non-discrimination, and equality before the law. However, neurorights are a legal advance because they are a form of regulation that protects human dignity.

A second criticism claims that the threats that neurorights are intended to neutralize are a legal fiction: they do not exist or are very distant. On this point, the legal literature defines legal fictions and allows them, as long as they contain gnoseological assumptions based on certain methodologically founded certainties (Campbell, 1983). At present, brain reading is only an experimental hypothesis confined to laboratories, not yet a mass reality. We may even be witnessing the beginnings of a mutation in ontology (Rose, 2016), for example in treating cognitive freedom as the reformulation of the right to freedom in its multiple dimensions (Ligthart, 2020). Behind it is the rationale that al-

1 See https://www.camara.cl/legislacion/ProyectosDeLey/tramitacion.aspx?prmID=14385&prmBOLETIN=13828-19

gorithms are able to manipulate our preferences for marketing purposes, which affects our privacy (Nissenbaum, 1998; Véliz, 2021), our cognitive freedom (Sententia, 2004), and our mental integrity (Lavazza, 2018). The need for regulation is thus not based on a potential danger, but on a disruption of what we expect artificial intelligence to do (Zuboff, 2015). Thus, cognitive freedom as a reformulation of other types of constitutionally guaranteed freedoms (freedom of conscience, freedom of inquiry, freedom of expression, freedom of religion) implies a presupposition of freedom of cognition that the conceptualization of neurorights protects, expands, and consolidates. In addition, the Santiago Court of Appeals has agreed to consider an action for protection based on the constitutional neurorights reform against the neurotechnology company Emotiv for appropriating the neural data of users. This action was declared admissible by the Supreme Court (Rol 49852-2022, Court of Appeals of Santiago), and makes it possible to strike down the claim that neurorights are a fictitious legal construction.

A third type of criticism notes that there are more pressing legislative priorities to be resolved, for example, the passage of a data protection law. Indeed, Bulletin 11092-07, addressing "personal data protection," was introduced to the Congress in 2017 as a modernization of Law No. 19.628.[2] It is true that there is a need to modernize data protection to international standards, such as the European GDPR, but the neurorights bill, although broadly converging with this regulation, is more specific to neurodata, that is, data collected by neurotechnological devices, especially with regard to the ethical use of the brain-computer interface (Vlek et al., 2012; Fouad et al., 2015; Goering et al., 2021; Naufel & Klein, 2020).

Following the enactment of the neurorights reform, there was another series of criticisms from the international academic community (Bublitz, 2022; Rommelfanger, Pustilnik, & Salles, 2022; Fins, 2022; Rainey, 2023). Cristof Bublitz, a specialist in criminal law at the University of Hamburg, who has been writing about neurolaw for more than a decade (Bublitz, 2022), speaks of an "interdisciplinary misunderstanding," asserting that "it should not be the scientists who are drafting the norms on neurorights" (Bublitz, 2022, p. 7), but jurists specialized in constitutional law. In Chile, he notes, these scientists are neurobiologists, a clear allusion to the influence of Rafael Yuste in the deliberations on the neurorights bill. It should be noted, however, that records of the deliberations show that constitutionalist law scholars and jurists from other branches of law were involved in the discussion, as well as experts from other disciplines, including philosophers, ethicists, and neurobiologists. The academics who supported the Chilean project left the academy and became activists who advised legislators in the drafting of the laws. In my particular case, I was invited because of my dissenting position, so it is not true that a biased group of academics were uncritically discussing the implications of neurorights.

The Chilean discussion of the neurorights reform came at a time of particular democratic vulnerability, since the prospect of a new constitution was being voted on. The reform was passed in an entirely democratic process that demonstrated that it was possible to have a dialogue while respecting the bases of democracy (Celag, 2022). A commission of 24 experts is now in search of a more consensual and less idiosyncratic constitutional text, and digital rights such as neurorights will again be discussed.

Rommelfanger, Pustilnik, and Salles (2022) allude to a conceptual ambiguity, although they recognize the trend towards regulation of neurotechnologies and in this context the concept of neurorights could be correct, as long as there is clarity. They also argue that the legislation has had a negative impact on mental health research in Chile, arguing that Chilean legislation aimed at protecting the vulnerable has had a negative impact on medical care and research (Ruiz et al., 2021; López-Silva & Madrid, 2021).

There are also the criticisms of the president of the American Neuroethics Society, Joseph Fins:

> *First, [neurorights] would be obliged to balance both positive and negative rights in the furtherance of human capabilities. Second, it would need to be future oriented and informed about the science it sought to regulate and not fall prey to science fiction fantasies that remain ungrounded in reality. Third, it would need to be specific and avoid generalizations that would lead to conceptual confusion and litigation that could forestall scientific progress. Finally, it would need to harmonize novel neurorights with long-established norms in international disability and human rights law. A failure to meet these criteria will destine any novel neurorights regime to the periphery. At this juncture Chile's nascent constitutional venture into neurorights fails to satisfy these criteria. While there yet may be a role for a more capacious and bivalent articulation of neurorights that accounts for capabilities and precedent, the current Chilean neurorights reforms are vague and premature. As such they should undergo additional scholarly scrutiny and should not be adopted by other jurisdictions. (Fins, 2022, p. 8).*

Fins's conclusion is that Chile's incipient neurorights reform does not meet these criteria, which will condemn any novel neurorights regime to irrelevance.

## RESULTS

The criticism that the neurorights law could have a negative impact on mental health research with those who cannot give consent on their own, as is the case of patients with alterations of consciousness or advanced Alzheimer's disease, has been discussed for more than a decade in Chile in light of a problematic article of Law No. 20.584, known as

2 See https://www.camara.cl/legislacion/ProyectosDeLey/tramitacion.aspx?prmID=11661&prmBoletin=11144-07

the "Law on the Rights and Duties of Patients," enacted in 2012. Article 28 of that law provides that "No mentally or intellectually disabled person who is unable to express his or her wishes may participate in scientific research." This provision rules out all biomedical research on people with alterations of consciousness or mental disabilities such as Alzheimer's disease, or those in a vegetative state (Valenzuela et al., 2015). The problem was partly remedied by the recent enactment of Law No. 21.331, "On the Recognition and Protection of the Rights of Persons in Mental Health Care" (Ministerio de Salud, 2021), although the new law still does not allow for research on persons without the capacity to consent. According to one analysis, "The law adds to the standards of the Helsinki Code, and safeguards are incorporated into informed consent, such as the prohibition of research on persons who might regain their capacity to consent to treatment, the duty to demonstrate minimal potential benefits and risks, and the possibility of advance consent, through advance directives for persons with neurodegenerative diseases" [Foros para el análisis de las implicancias de la ley 21.331, 2021; Universidad de Chile (2021)].

Another recent criticism (Rainey, 2023) argues that the neurorights could hinder attention to the regulation of neurological data more than it promotes human rights. The argument has contributed to a needed discussion in various fields about why we should protect mental integrity from the disruptive use of neurotechnologies, not only from the perspective of neuroethics, but also from a legal point of view. It is clear that the authors of the foundational texts of neurorights (Ienca, 2021) speak of reconfigurations of human rights, moving away from the novel refoundation proposal of neurorights, so that Hohfeld's magnifying glass could also be said to contribute to clarify the conceptual discussion, but at the same time further complicates the discussion with a new concept of neuroprivileges. It could be that we are facing a language game, a pendulum that swings between positions until it reaches the consensus necessary for an advance in the dialogue.

In the UK, the Regulatory Horizons Council has recently prepared a document that adopts a medical model similar to that of Chile, which would regulate neurotechnologies not only for therapeutic use, but also for commercial use, describing such regulation as "a proportionate regulatory framework that encourages the safe commercialization of medical neurotechnologies and addresses under-regulation concerns of non-medical neurotechnologies, and a governance framework to address the forward-looking ethical challenges neurotechnologies may pose in the future" (Regulatory Horizons Council, 2022). What is important about the Chilean regulation is that it emphasizes regulation of the recreational uses of neurotechnologies referred to as neuroenhancement (Maslen et al., 2015; Wexler, 2015; Cornejo Plaza, 2021b) and the ethical and regulatory issues raised by direct-to-consumer marketing of enhancement products (Goering, 2021).

### Ethical Implications for Mental Health

The real challenge for mental health research lies in the reformulation of Article 28 of Law No. 20.584 and not in the enactment of neurorights at the constitutional level. Biomedical research in mental health is governed by health legislation. The law on neurorights does not interfere in this area, but to some extent remedies the disruptive uses of neurotechnologies that are not therapeutic but commercial. In this sense, the prohibition in the neurorights law of the use of neurodata without the user's consent is a legislative advance.

Law No. 21.331 introduced changes to the Sanitary Code with an impact on mental health. It amended Article 25 of Law No. 20.584, enacted in 2012, as follows:

4. Article 28 is replaced by the following:

> *Article 28.- Biomedical research may not be carried out on adults who are not physically or mentally capable of expressing their consent or for whom it is not possible to know their preference, unless the physical or mental condition that prevents granting informed consent or expressing their preference is a necessary characteristic of the investigated group. In these cases, a person whose health condition is treatable may not be involved in research without consent, so that they can regain their capacity to consent. In these circumstances, in addition to giving full compliance with the norms contained in Law No. 20.120, on scientific research on the human being and its genome, and prohibiting human cloning, and in the Sanitary Code, as appropriate. The research protocol must contain the specific reasons for including individuals with a disease that does not allow them to express their consent or manifest their show that the research involves a potential direct benefit for the person and implies minimal risks for them. A favorable report from an accredited scientific ethics committee and the authorization of the Regional Secretary of Health must be obtained in advance. In these cases, the members of the committee that evaluates the project may not be linked directly or indirectly with the center or institution in which the research will be carried out, or with the principal investigator or the sponsor of the project. The consent or expression of preference must be obtained as soon as possible from the person who has recovered their physical or mental capacity to grant said consent or express their preference. Persons with neurodegenerative or psychiatric diseases may give their informed consent in advance to be test subjects in future research, when they are no longer in a position to consent or express their preference* (Law No. 21.331 - Ministerio de Salud, 2021).

Biomedical research on minors is governed by the provisions of Law No. 20.120, which provide that their refusal to participate or continue in a study should be respected.

## DISCUSSION AND CONCLUSION

The enactment of neurorights as hard law is not detrimental to the field of mental health. A lack of regulation in non-medical use could lead to problems related to safety

(e.g., in relation to brain function modulation), privacy, misleading information, accessibility, and confidentiality. All brain modulation devices, both invasive and non-invasive, should be regulated as medical devices, regardless of the purpose for which they are marketed, as proposed by the European Commission. The recommendation of specialists is to regulate the inappropriate use of neurotechnologies, but the manner adopted must ensure the fundamental rights of individuals, regulatory integration, and technological innovation, and biomedical research should be carried out under the biomedical legislation. The legislation that is altered is that of consumer law: damage caused by a neurotechnological device for non-therapeutic use is no longer a matter of common law, but comes under a regulation of neurorights that protects mental integrity and cognitive freedom. The definition of neurorights is a task of jurisprudence. The legislation defines certain elements in a developing area of law, providing it with legitimacy and effectiveness.

Some authors have described the regulation of neurorights as a threat to an ecosystem that uses neurotechnologies. However, we conclude that despite these criticisms, from an ethical point of view it is not. Rather, it provides protection to people within the complex system of neurotechnologies.

The concept of neurorights can catalyze the normal evolution of the law in relation to the disruptive use of neurotechnologies and artificial intelligence, which has been accelerated by the COVID-19 pandemic. It has been adopted in Chile through democratic mechanisms, not behind the back of the people. In the deliberations on the proposed legislation, all parties were heard who wished to contribute their views; the proceedings were public and interdisciplinary, and included constitutional and civil legal scholars, experts in human rights, bioethicists, neurobiologists, and others.

Neurorights are a contribution of reflection and courage in the face of a future full of questions, challenges, and opportunities for improving our personal and social well-being. Discussions on neurorights must continue at all levels: political, academic and societal. There are continuing issues regarding the conceptual definitions of different neurorights and the new taxonomies arising from new technologies, and the task of addressing them is one for legal scholars and other academics (Herrera-Ferrá et al., 2022; Muñoz & Marinaro, 2022). This regulation provides a robust response relying on the biomedical model in the face of unregulated neuroenhancers without appropriate consumer legislation. Because it derives from the biomedical model, the regulation of neurotechnologies is no more restrictive than other regulations in Chile, which did have a negative impact on mental health research on vulnerable groups. This regulation does not affect research on mental health, but sets high standards for the commercial use of neurotechnologies.

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The author declare they have no conflicts of interest.

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