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Artificial Intelligence in Health and Bioethical Implications

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Abstract: **Artificial Intelligence in Health and Bioethical Implications**
The rise of Artificial Intelligence (AI) in the twenty-first century, notably in its application to health and neurotechnologies, represents a transformative milestone with undeniable potential to enhance the human condition, from diagnosing complex diseases to restoring motor functions. However, this rapid innovation imposes a central ethical-legal dilemma: how to reconcile technological advancement with the non-negotiable protection of human dignity and bioethical principles. This article examines the inherent risks at this intersection, identifying algorithmic opacity (black box), discriminatory biases, and threats to autonomy and privacy – particularly neural data – as the main points of vulnerability. It employs a methodology of literature review and documentary analysis of national regulatory frameworks, such as the Brazilian General Data Protection Law (Lei Geral de Proteção de Dados – LGPD), and international frameworks, such as those of UNESCO (United Nations Educational, Scientific and Cultural Organization), the OECD (Organisation for Economic Co-operation and Development), and the EU General Data Protection Regulation (GDPR), in pursuit of solutions to mitigate negative impacts.

Keywords: Bioethics, Artificial Intelligence, Health, Fundamental Rights, Regulation.

Summary: 1. Introduction – 2. Theoretical and Conceptual Framework – 3. Bioethical Implications of AI in Health – 4. Challenges and Future Perspectives – 5. Conclusion.

1. Introduction

The ascendance of Artificial Intelligence (AI) is one of the most strategic and transformative developments of the twenty-first century, profoundly reshaping contemporary society. AI represents a conceptual break comparable to major scientific revolutions, as it challenges the boundary between machine operations and the human mind. Powered by the massification of data (big data) and the development of sophisticated algorithms, AI has become an indispensable tool with the potential to solve major societal challenges, especially in the health sector.

Indeed, it is in the health sector that the impact of AI and related technologies, such as neurotechnologies, assumes particular prominence today. AI enables the analysis of large datasets, allowing for personalized therapeutic approaches and more accurate diagnoses. Although sources describe in more detail the intersection

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of AI with neurotechnologies for treating neurological, psychiatric disorders, and for restoring functions, AI is more broadly recognized for assisting diagnosis by identifying patterns and estimating probabilities at high speed. Its transformative potential aims to enhance the human condition and can greatly support the targeting of treatments and the cure of diseases.

Despite its undeniable benefits, AI's advance raises challenges linked to ethical-legal issues. AI's complexity, autonomy, and opacity complicate the application of existing regulation. AI systems may be opaque, with the logic of their operation remaining concealed. This opacity compromises the principle of transparency and prevents data subjects from exercising control over their information. For diagnostic purposes, for example, the use of "black box" technologies should be discouraged, as a lack of clarity can lead to biased information and inaccurate diagnoses.

Discriminatory biases may arise from errors, flaws in technical design, or from biased training data, threatening the accuracy of results. Simply removing sensitive variables from datasets may not suffice to avoid discriminatory effects. In the context of algorithmic predictions applied to human behavior, forecasts based on past data can reinforce patterns of discrimination and perpetuate inequality.

Moreover, AI expands the possibilities to track and analyze day-to-day habits, increasing the risks of violations of data protection and privacy. The central dilemma, therefore, is how to ensure that technological innovation occurs ethically and safely without compromising fundamental human values. As a tool that affects social relations, technology must be brought into legal debates to be harmonized with human rights and to avoid their infringement. As a form of applied ethics, AI ethics should aim to curb risks related to human dignity, including the protection of privacy and personal data.

Safeguarding human dignity is the foundation for ensuring informational self-determination and non-discrimination. Accordingly, the research problem can be stated as follows: how to reconcile the rapid advance of technological innovation, especially AI applied to health, with the non-negotiable protection of human dignity and bioethical principles, ensuring that development serves humanity rather than undermining autonomy and integrity?

To that end, the study seeks to explore traditional bioethical principles (beneficence, non-maleficence, autonomy, and justice) and their expansion to mitigate the ethical dilemmas inherent in AI's use in sensitive contexts such as health; to map ethical-legal responses by analyzing how regulatory frameworks address risks of error, bias, and algorithmic opacity; and to identify safeguards capable of ensuring transparency, explainability, accountability, and human oversight in the development and deployment of AI systems in health.

The methodology employed is a literature review and documentary analysis of exemplary international and national regulatory instruments. Documents from international organizations such as the United Nations (UN), including UNESCO, the OECD, and the Organization of American States (OAS), will be examined. The study will also address European Union guidelines (e.g., the White Paper on

Artificial Intelligence and the Ethics Guidelines for Trustworthy Artificial Intelligence) and initiatives in the United States. Complementarily, national legislation such as the LGPD and Chile's pioneering regulation of neurorights will be analyzed.

2. Theoretical and Conceptual Framework

The exponential advance of digital technology has redefined contemporary society by establishing an informational paradigm in which big data and AI have become ubiquitous and strategic tools[1]. AI, in particular, is a general-purpose technology that performs intellectual processes characteristic of human beings, such as reasoning, generalizing, or learning from experience, by executing actions for which it was not explicitly programmed[2].

In health, AI becomes indispensable by enabling the processing and interpretation of large datasets, delivering a level of analysis and predictability unattainable by traditional methods. Big data embodies a paradigm and framework to support decision-making, being the pattern recognition or correlations in complex datasets its central aspect[3].

Machine Learning (ML) is a set of algorithms that identify patterns in data in order to build and refine mathematical models that can be used to make predictions and derive insights. ML is already actively used for diagnostics and precision medicine[4]. ML has two main subgroups: supervised learning (criteria parameterized by humans) and Deep Learning (DL), which is unsupervised. DL, made possible by neural networks, can generate correlation patterns that are independent from human reasoning, allowing computers to "see" and "distinguish" objects and text in images and video. However, the complex structure of deep learning algorithms increases opacity (the "black box" problem), which makes it difficult to explain how systems achieve specific outputs[5].

AI has the potential to foster disease cures and social welfare, and it is applied across several fronts in health. Practically, AI assists diagnosis by recognizing patterns and estimating probabilities at high speed. AI is being trained for complex

[1] J. Abrusio, *Proteção de dados na cultura do algoritmo*, D'Plácido, Belo Horizonte, 2020, p. 23.
[2] É. Antunes Naves, *Bioethics and artificial intelligence: a current overview of the literature*, UnitedHealth Group Brasil, São Paulo, 2020.
[3] Agata C. Amato Mangiameli, "Intelligenza artificiale, big data e nuovi diritti", in *Rivista italiana di informatica e diritto*, (2022), n. 1, pp. 93-101.
[4] A. Gutierrez, "É possível confiar em um sistema de Inteligência Artificial? Práticas em torno da melhoria da sua confiança, segurança e evidências de accountability", in A. Frazão, C. Mulholland (coord.), *Inteligência Artificial e Direito*, Revista dos Tribunais, São Paulo, 2019, p. 85.
[5] J. Singh, I. Walden, J. Crowcroft, J. Bacon, "Responsibility and machine learning: part of a process", in https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2860048.

diagnostics, such as in oncology, and it is used to accelerate triage and assign priorities to patients in clinical settings[6].

The intersection of AI with neurotechnologies, which enable advanced brain mapping, is connected to innovations in Brain-Computer Interfaces (BCIs)[7], which help patients recover motor functions and control external devices (such as smartphones or prostheses). Many of these devices are wearables which, through electroencephalography (EEG) and AI, allow real-time interpretation of complex patterns of brain activity[8].

In light of these technological advances, bioethics emerges as an essential field to address the ethical challenges that arise. AI must be developed in ways that respect ethical values and principles[9].

Modern bioethics is structured around the four fundamental principles developed by Beauchamp and Childress[10]. These principles serve as a guide to identify and mitigate the ethical dilemmas inherent in the development and use of emerging technologies – such as neurotechnologies and the use of AI[11], namely:

1. Beneficence: ensures that technology and health interventions generate clear benefits to individuals by promoting health, well-being, and quality of life.

2. Non-Maleficence: imposes a duty to avoid harm, which is as important as (or even more important than) promoting benefits, and requiring robust safety mechanisms aligned with ethical standards.

3. Autonomy: guarantees that individuals maintain control over decisions that affect them; in digital health, this entails clear informed consent that allows patients to have the final word and ongoing control over the use of their neural data and mental processes; and

4. Justice: ensures equitable access to treatments and technologies, preventing innovations from exacerbating social or economic inequalities, which is central to international recommendations on inclusion and diversity in technological development[12].

[6] C. Tavares De Albuquerque, "Violência psicológica e novas possibilidades em neurociências", in C. Pintarelli, J. Abrusio (coord.), *Neurodireitos*, D'Plácido, Belo Horizonte, 2025, p. 135.
[7] G. Bresciani Silva, "Neurodireitos e a eficácia horizontal dos direitos fundamentais na relação de trabalho", in C. Pintarelli, J. Abrusio (coord.), *op. cit.*, p. 99.
[8] V. Ceolin Dallasta Del Grossi, "Crianças e adolescentes no meio neurotecnológico: entre as novas fronteiras e as novas barreiras impostas pela tecnologia e pelo respeito aos direitos humanos", in C. Pintarelli, J. Abrusio (coord.), *op. cit.*, p. 145.
[9] É. Antunes Naves, *op. cit*.
[10] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, "Governança corporativa e neurodireitos", in C. Pintarelli, J. Abrusio (coord.), *op. cit.*, p. 195.
[11] T.L. Beauchamp, J.F. Childress, *Principles of Biomedical Ethics*, Oxford University Press, New York, 2013.
[12] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit*.

Beyond the traditional principles, debate on AI ethics incorporates elements such as explainability, responsibility (accountability), and equity, which extend bioethical practice to ensure transparency and mitigate algorithmic bias[13].

Technological development, especially in neurotechnologies, should pursue sustainability and a commitment to future generations[14]. The concern is that neurotechnologies and AI directly interact with the mind, raising questions about how development will be conducted and used in relation to fundamental rights, thereby requiring preventive and cross-sector regulatory approaches to ensure technological advancement promotes well-being and social coexistence[15].

The debate on AI and digital health must be grounded in human dignity, an inalienable foundation for fundamental rights. Human rights represent the minimum conditions guaranteed to individuals to live with dignity in society[16]. The State, as guardian of these rights, should promote a regulatory environment that stimulates innovation while protecting human dignity[17].

A human-centered approach seeks to ensure that AI systems do not result in decisions with discriminatory bias, since algorithms may inherit the bias of training data and the values of their designers. Safeguarding dignity and combating algorithmic discrimination are therefore essential pillars for building a trustworthy AI[18].

3. Bioethical Implications of AI in Health

The intersection between AI and health raises profound bioethical dilemmas, as technology directly interacts with human intimacy, privacy, and autonomy, especially when dealing with hypersensitive data such as neural data[19]. Developing trustworthy AI requires it to be, cumulatively, lawful, ethical, and robust, even though the risk of unintended harm persists. In this context, bioethics extends its foundational principles to ensure that technological innovation proceeds in accordance with respect for human dignity.

The principle of autonomy ensures that individuals retain control over decisions that affect them, with clarity as to the risks involved so they can make informed decisions[20]. In digital health, autonomy translates into the individual's

[13] *Ibidem*.
[14] V. Ceolin Dallasta Del Grossi, *op. cit*.
[15] *Ibidem*.
[16] G. Bresciani Silva, *op. cit*.
[17] I.F. Barreto Junior, L. Tavares Simão, V. Sampaio, "Inteligência artificial, neurodados e proteção de dados hipersensíveis", in C. Pintarelli, J. Abrusio (coord.), *op. cit.*, p. 85.
[18] European Commission, "Ethics guidelines for trustworthy AI", in https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai>.
[19] I.F. Barreto Junior, L. Tavares Simão, V. Sampaio, *op. cit.*, p. 81.
[20] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit.*

sovereignty and freedom in decision-making[21]. However, algorithmic mediation and the complexity of AI systems may undermine the effectiveness of this principle.

The growing use of AI for profiling and for automated decision-making, even in the public sector and in high-risk applications such as health, means that decisions affecting people's lives are increasingly made by computational systems. In many cases, the logic underlying a given outcome remains inaccessible or opaque (the black box problem).

This opacity – common in deep learning algorithms – compromises the individual's ability to understand or challenge decisions made about them. One of the great dangers of automated decisions is the false appearance of greater objectivity, even though they are not fundamentally more logical or impartial than human decisions[22]. The lack of clarity over how systems reach certain outputs hinders the defense of individual rights. In this regard, the EU GDPR recognizes the right not to be subject to decisions based solely on automated processing that produce legal effects or similarly significantly affect an individual.

Under Brazil's LGPD, data subjects have the right to request a review of decisions made solely on the basis of automated processing that affect their interests, including decisions intended to define their personal, professional, consumer, and credit profiles or aspects of their personality. Controllers must also provide, whenever requested, clear and adequate information about the criteria and procedures used for automated decisions, subject to trade and industrial secrets; if such information is withheld on secrecy grounds, the national authority may conduct audits to verify discriminatory aspects in automated processing.

Informed consent is a pillar of bioethics and of neurorights. However, in the digital environment and the algorithmic culture, it often proves insufficient or ineffective. For consent to be valid, the data subject must express it freely, in an informed and unequivocal manner. The informational asymmetry between users and large technology platforms, however, is exacerbated by algorithms. Individuals may not be in a position to consent appropriately, as cognitive and volitional limitations hinder a real understanding of what algorithmic use in automated decision-making entails.

Consent for sensitive data, such as neural data, should be continuous and dynamic, allowing users to review and update permissions over time. AI regulatory frameworks, such as European guidelines, require controllers to demonstrate that the data subject understands exactly what they are consenting to. The burden of privacy protection cannot fall solely on the individual, resulting in an unequal bargain[23].

The principle of justice requires that AI development promote equitable access to treatments and technologies, preventing the increase of social inequalities

[21] J. Abrusio, F. Médici Guerra Martins, "A regulamentaçao das nanotecnologias: desafios e riscos", in C. Pintarelli, Ead. (coord.), *op. cit.*, p. 278.
[22] J. Abrusio, *Proteção de dados na cultura do algoritmo*, cit.
[23] *Ibidem*.

and discrimination. However, AI can exacerbate existing discrimination and inequalities[24].

AI systems can produce discriminatory bias that violates fundamental rights. Such bias may result from flaws in technical design, but more often is inherited from biased training data[25]. Because algorithms replicate social values, they can reproduce human prejudice at large scale.

Algorithmic discrimination threatens equal opportunity, potentially depriving a person of employment, credit, or, in health, a correct diagnosis and the proper treatment. AI may exhibit racial and gender biases, as seen in facial recognition programs with high error rates in gender determination for darker-skinned women.

In addition, reliance on algorithmic predictions based on past human behavior leads to the "fossilization problem." This effect reinforces patterns of discrimination and inequality, hardens social reality, and limits the possibilities for change. Removing sensitive variables (such as race or gender) from training data may not suffice to avoid discriminatory outcomes, because bias can enter through other associations (such as postal codes).

Justice in AI manifests as the right to fair, non-discriminatory access to these technologies. If benefits such as neural rehabilitation and cognitive enhancement are not democratized, there is a risk of technological concentration in the hands of a few and a deepening of inequality.

Organizations should pay special attention to protecting vulnerable groups (children, persons with disabilities, and historically disadvantaged or at-risk groups). A lack of clear regulation may result in abusive practices where companies exploit vulnerable populations, particularly in countries with limited technological access. AI development should be guided by diversity and equity.

The principles of beneficence and non-maleficence require, respectively, the promotion of benefits and the prevention of harms. AI is recognized for its transformative potential in health. The principle of beneficence is evident in applications that improve health and quality of life[26].

AI assists in diagnosis through pattern recognition and high-speed probability estimation. Generative AI can aggregate a much greater complexity of data than human cognition can process. It can be trained to support physicians in diagnostic decision-making, accelerate patient triage, or analyze medical images[27].

The incorporation of AI into neurotechnologies, for instance, has advanced the identification of brain patterns, facilitating personalized therapeutic approaches and more accurate diagnoses. Neurotechnologies themselves open countless

[24] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit*.
[25] R. Caplan, J. Donovan, L. Hanson, J. Matthews, "Algorithmic accountability: a primer", in *Data & Society*, April 18, 2018 (https://datasociety.net/output/algorithmic-accountability-a-primer/).
[26] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit*.
[27] C. Tavares De Albuquerque, *op. cit*.

possibilities for progress for persons with disabilities and severe disorders, such as treating neurological diseases and restoring motor functions[28].

Non-maleficence requires robust safety mechanisms to mitigate risks. However, AI, especially in medical applications, presents safety and reliability risks.

Failures in algorithms used for medical diagnosis or in surgical assistance carry harm potentials that may involve people's lives. AI systems, especially those classified as high-risk (such as in health), must be technically robust and accurate[29]. If there is any bias in the data used to train an algorithm, it will result in incorrect decisions and inaccurate diagnoses.

The use of opaque technologies (black box) must be accompanied by heightened safeguards in healthcare settings because they fail to clearly demonstrate their functioning, which may lead to biased information and incorrect diagnoses[30]. If AI fails, patient safety may be compromised, and clinicians may lose time correcting errors or over investigating. To ensure patient safety, AI developers must build more transparent and trustworthy solutions. Technical robustness and safety are required for AI systems to be considered trustworthy.

4. Challenges and Future Perspectives

The exponential advance of AI systems, especially in sensitive areas such as health and the processing of neural data, imposes complex regulatory challenges that demand a global, coordinated, and profoundly human-centered response. The speed of technological innovation tends to widen the gap between real-world developments and what is enshrined in legal systems, making it urgent to build a robust and dynamic regulatory ecosystem[31].

AI will increasingly be applied in domains where ethical considerations are crucial, as in health, cutting-edge medical treatments, and more accurate diagnostics through analysis of brain patterns. One of the risks, however, is that technologies initially designed for neurological rehabilitation or other clinical purposes may be exploited for uses not foreseen or disclosed[32].

The European Commission has already highlighted health as a "critical sector" for AI applications. Consequently, AI technologies applied in "critical sectors" should be subject to stricter rules, including conformity assessments and guaranteed possibilities for human intervention and control[33].

[28] V. Ceolin Dallasta Del Grossi, *op. cit*.
[29] J. Abrusio, *Proteção de dados na cultura do algoritmo*, cit., pp. 17 e 23.
[30] C. Tavares De Albuquerque, *op. cit*.
[31] I.F. Barreto Junior, L. Tavares Simão, V. Sampaio, *op. cit.*, p. 92.
[32] G.A. Saavedra, C.B. Santorsula, "Nanotecnologias e o Mercado da cognição: Riscos de Brainhacking e Construção de Neurodireitos", in C. Pintarelli, J. Abrusio (coord.), *op. cit.*, p. 52.
[33] J. Abrusio, *Proteção de dados na cultura do algoritmo*, cit.

To address regulatory dispersion in a domain with global characteristics, AI's future regulatory framework should define mandatory legal requirements that can be specified through standards. These standards should be applied in a focused and proportionate manner to high-risk AI applications.

The development of an ethical AI effort, including the adoption of ethical standards in data processing, can support data protection authorities in safeguarding individual rights and can help in meeting legal requirements. The European Commission's White Paper proposed the creation of standard rules for voluntary adoption by companies. Moreover, given that data protection and privacy are fundamental to human dignity, Europe has exerted significant influence and is considered a cradle for replicating and setting gold standards for privacy and data protection worldwide.

Building a global regulatory consensus is challenging, as legal solutions often reflect national and regional legal and cultural differences[34]. Nonetheless, the need for regulation in the face of globally characteristic issues such as AI requires striving for a harmonized global framework.

Harmonization has been promoted through international soft law frameworks, such as the Universal Declaration of Human Rights (which has already had global effect) and the Organization for Economic Co-operation and Development's guidelines (OCDE)[35]. The OECD has published a Recommendation on Responsible Innovation in Neurotechnology (2019), and the G20 has endorsed the OECD AI Principles, which demonstrates an attempt to establish an intergovernmental standard[36].

The evolution of data protection regulation shows that the paradigm of control, providing general principles and legal mechanisms to grant individuals greater control over their information, has been the convergent aspect of international instruments such as the International Standards on the Protection of Personal Data adopted in Madrid. The EU General Data Protection Regulation (GDPR) is a prime example of a norm that strongly influences global regulation on the subject, forming a genuine platform for global partnerships.

In the field of neurorights, UNESCO has published a report calling for a global regulatory model[37]. The OAS Declaration of Inter-American Principles on Neuroscience, Neurotechnology and Human Rights, while non-binding, sets

[34] C. Bradley, J.L. Goldsmith, O.A. Hathaway, "The Rise of Nonbinding International Agreements: An Empirical, Comparative, and Normative Analysis", in *The University of Chicago Law Review*, 90 (2023), n. 5 (https://doi.org/10.2139/ssrn.4023641).

[35] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit*., p. 193.

[36] Organisation for Economic Co-operation and Development (OCDE), "Recommendation of the Council on Responsible Innovation in Neurotechnology", in https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm.

[37] Unesco, "The risks and challenges of neurotechnologies for human rights", in https://unesdoc.unesco.org/ark:/48223/pf0000384185, New York, 2023.

guidelines to ensure that scientific advances respect neurorights[38]. Data protection legislation will need to adapt and update itself to keep pace with the advancement of neurotechnologies.

Interaction based on algorithmic profiling may exacerbate informational imbalances between governments and companies, on one hand, and individuals, on the other. Consequently, public and private organizations that are "data-rich" will bear greater ethical responsibilities toward citizens and customers.

The regulatory challenge demands cooperation and the engagement of multiple stakeholders. The European Commission has proposed establishing a European AI governance structure in the form of a cooperation framework among competent national authorities. This structure aims to prevent fragmentation of responsibilities and to enhance Member States' capabilities, serving as a forum for regular exchange of information and best practices.

Additionally, in neurotechnologies, the Morningside Group (Columbia University), led by Rafael Yuste, proposed four priority areas of protection that gave rise to the concept of neurorights: ensuring the privacy and consent of neural data; protecting self-determination and sense of identity; ensuring equitable access to neurological enhancements; and combating prejudice (bias)[39]. Chile was the first country to constitutionalize these rights. In Brazil, the State of Rio Grande do Sul already provides for neurorights protections in its State Constitution, and several other regulations are poised to become effective[40]. These national and international standards demonstrate the public and private sectors' social obligation to articulate ethical positions that curb risks to human dignity.

Companies that develop neurotechnologies must assume a central role in building ethical and regulatory solutions. The regulatory pathway should reconcile the advantages of state regulation (which may be enforced by coercion in the public interest) with self-regulation. Co-regulation – or regulated self-regulation – works along this line, focusing on industry self-organization while encouraging general parameters of public interest cherished by the State and society[41].

The GDPR promises broader cooperation between authorities and data controllers both within the EU and internationally, which is expected to encourage controllers inside and outside the EU to take the initiative in developing standards. In the specific context of neurorights and neurotechnologies, international cooperation will be essential to address global challenges and to avoid regulatory gaps created by a lack of norms in some countries. Creating an international body

[38] Organization of American States (OAS), "Inter-American Declaration of Principles on Neurosciences, Neurotechnologies, and Human Rights", in https://www.oas.org/es/sla/cji/docs/CJI-RES_281_CII-O-23_corr1_ESP.pdf.

[39] R. Yuste, *et al*., "Four ethical priorities for neurotechnologies and AI", in *Nature*, 551 (2017), pp. 159-163 (https://www.nature.com/articles/551159a).

[40] L. Rocha Garcia, A. Fuke Fachinetti, L. Dall'Agnese, *op. cit*.

[41] J. Maranhão, R. Campos, "Exercício de autorregulação regulada das redes sociais no Brasil", in N. Campos Nery, G. Abboud (orgs.), *Fake news e regulação*, Revista dos Tribunais, São Paulo, 2018.

dedicated to neurotechnologies would be relevant to set guidelines and ethical standards and to foster the development of global standards.

In the context of neurotechnologies, law should act as a balancing factor, ensuring that the human mind remains a space of inalienable freedom and that benefits are accessible without compromising mental liberty and personal identity[42]. The proposition of neurorights – such as mental privacy, personal identity, and free will – aims precisely to safeguard the human mind and brain activity, ensuring that technological development serves the human subject and does not pose risks of social exclusion or discrimination. To this end, it is crucial that the principle of human autonomy be respected and that the development and use of AI systems satisfy requirements such as human agency and oversight.

AI systems must be designed to respect the rule of law, human rights, and democratic values, including dignity, liberty, autonomy, privacy and data protection, non-discrimination, diversity, equality, and social justice. The European Commission has proposed a strategy that places humans at the center of AI development, encouraging technology to contribute to solving major global challenges.

5. Conclusion

The investigation into reconciling the rapid advance of AI in the health sector with the non-negotiable protection of human dignity and bioethical principles demonstrates that the central dilemma lies not in restricting innovation but in the urgent need to build a robust, dynamic, and human-centered regulatory ecosystem. The analysis of AI's implications, particularly at its intersection with neurotechnologies, confirms that, while the beneficial potential for enhancing the human condition is exponential, the risks associated with algorithmic opacity (black box), discriminatory biases, and vulnerabilities in autonomy and privacy demand safeguards that transcend traditional legal structures.

The study achieved its objectives by showing how classical bioethical principles – beneficence, non-maleficence, autonomy, and justice – must be expanded and reinterpreted in the context of digital health. The principle of autonomy requires overcoming a static model of informed consent and moving toward continuous, dynamic consent when dealing with hypersensitive data, such as neural data, given informational asymmetry and the complexity of automated decisions. The principle of justice requires a firm stance against algorithmic discrimination and the "fossilization problem," ensuring that AI does not reinforce patterns of inequality but instead promotes equitable access to its benefits. Non-maleficence requires AI, especially in applications classified as high-risk in health,

[42] C. Pintarelli, "A livre manifestação do pensamento no cenário da neurotecnologia: a proteção ao pensar como proteção do pluralismo politico", in Ead., J. Abrusio (coord.), *op. cit.*, p. 1.

to be technically robust and reliable, discouraging the use of black-box systems in diagnostic settings.

Mapping legal and ethical responses reveals a convergent, albeit dispersed, global effort. Soft law initiatives from international organizations, such as the OECD Recommendation on Responsible Innovation in Neurotechnology and UNESCO and OAS reports, demonstrate the pursuit of a harmonized framework of guidelines. The EU General Data Protection Regulation's (GDPR) influence establishes a gold standard of regulation that emphasizes the individual's control over personal data and the right not to be subject to exclusively automated decision-making. This control paradigm consolidates itself as the most promising regulatory aspect.

The principal future perspective aligned with the protection of human dignity lies in implementing mechanisms that ensure transparency, explainability, accountability, and human oversight in AI systems. The proposal to set mandatory legal requirements and to define standards applied proportionally to high-risk technologies – as suggested by the European Commission – is the safest pathway to mitigate unintended harms.

Consubstantiating such safeguards under the rubric of neurorights, with Chile leading the movement to constitutionalize protections for the mind and brain activity, represents regulatory vanguardism. These rights – such as mental privacy, personal identity, and free will – aim to ensure that the human mind remains a domain of inalienable freedom, with law acting as a balancing factor between innovation and integrity.

In sum, regulating AI in health is not a constraint but an ethical and legal imperative to ensure that technological progress fulfills its purpose: to serve the human person. The solution requires international cooperation, co-regulation (reconciling state regulation and industry self-regulation), and the ethical commitment of both public and private sectors to place the individual at the center of AI development.