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THE EVOLUTION OF THE REGULATION OF ARTIFICIAL INTELLIGENCE IN MEDICINE: A COMPARATIVE PERSPECTIVE AMONG BRAZIL, EUROPE, AND THE UNITED STATES ¹

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Abstract

Objective: This study aims to analyze the evolution of the regulation of artificial intelligence (AI) applied to medicine, comparing the regulatory models adopted in the United States and the European Union with those developed in Brazil, and to examine the impacts of these regulatory frameworks on the physician-patient relationship. **Methodology:** The research adopts a qualitative, descriptive, and comparative approach, based on a narrative review of the literature and analysis of primary legal sources, including the European General Data Protection Regulation (GDPR) and the Artificial Intelligence Act (AI Act), the United States' Federal Food, Drug, and Cosmetic Act (FDCA), the 21st Century Cures Act, and FDA guidance documents, as well as Brazil's General Personal Data Protection Law (LGPD) and the Brazilian Artificial Intelligence Strategy (EBIA). The analysis is organized into four thematic sections addressing, respectively, the definition and applications of AI in health, the ethical and legal challenges involved, the international and Brazilian regulatory landscape, and concluding perspectives. **Results:** The findings indicate that the European Union has established the most structured regulatory framework, through a risk-based model under the AI Act that classifies most AI-based medical devices as high-risk, subjecting them to strict transparency, human oversight, and conformity assessment requirements. The United States, in turn, relies on a flexible, iterative regulatory approach centered on the FDA, which distinguishes software functions excluded from the definition of a medical device from those subject to oversight, while facing ongoing challenges related to algorithmic explainability, interoperability, and the adaptation of tort

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liability. Brazil, by contrast, still lacks a specific regulatory framework for AI in health; its normative foundation rests primarily on the LGPD, complemented by soft-law instruments and institutional strategies such as the EBIA, reflecting an incipient but progressively converging regulatory trajectory. Across all three jurisdictions, transparency and algorithmic explainability emerge as central principles for ensuring patient autonomy, accountability, and trust in AI-mediated clinical decision-making.

Keywords: Artificial intelligence; Health law; AI regulation; Medical devices; Algorithmic transparency; Comparative law; Patient autonomy.

Introduction

Artificial intelligence (AI) has established itself as a technology of growing relevance in the field of health, driving transformations in diagnostic, treatment, and clinical management processes. However, the rapid evolution of these tools raises important challenges related to safety, ethics, and legal liability. In this context, the regulation of AI applied to health has received increasing attention from governmental bodies and regulatory entities in different countries, given the need to reconcile the encouragement of technological innovation with patient protection. Moreover, the incorporation of AI into medical practice challenges traditional paradigms of the physician-patient relationship, particularly with regard to trust, communication, autonomy, and human participation in clinical decisions.

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This article aims to analyze the evolution of AI regulation in the medical field, comparing the regulatory models existing in the United States and Europe with those adopted in Brazil, in addition to examining the impacts of these changes on the relationship between physicians and patients. To this end, Chapter 1 presents the definition of AI, its applications in health, and the main technological developments. Chapter 2 discusses the ethical and legal challenges involved. Chapter 3 discusses the evolution of AI regulation in health, addressing the international landscape, Brazilian regulation, and the main regulatory challenges. Finally, Chapter 4 presents the conclusions and perspectives, highlighting the importance of public policies and regulatory practices that promote an ethical, safe, and humanized application of artificial intelligence in medicine.

It is hoped that this work will contribute to the understanding of the role of public policies in promoting an ethical and safe application of artificial intelligence in medicine, while preserving the humanization of care.

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1. Definition and Applications of Artificial Intelligence in Health

Artificial intelligence consists of computational systems capable of performing tasks typical of human intelligence, such as learning, reasoning, and decision-making. In the context of health, AI has been applied on several fronts, from the management of large volumes of data to support for medical decision-making, offering the potential to increase efficiency, reduce errors, and improve patient care. ⁽¹⁾

The concept of Big Data is central to the functioning of artificial intelligence in health, which basically consists of the challenge of managing and analyzing a large volume of data that exceeds conventional processing and storage capacities. The advancement of Big Data has driven significant transformations in the health sector, particularly in research using data mining techniques and in the integration of multiple sources of clinical information, such as medical records, images, and health literature, among others. ⁽²⁾

AI applications can be organized into three main axes: machine learning, which consists of the use of techniques that allow systems to learn from processed data, identifying patterns and making decisions with minimal human intervention, becoming increasingly

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resilient and adaptive; deep learning, which consists of the use of Artificial Neural Networks (ANNs), mathematically modeling the structure of human neurons — each unit of the ANN performs operations on local data connected by channels with predetermined weights, allowing the intelligent behavior of the network to emerge from the interactions between its processing units; and natural language processing (NLP), which consists of enabling computational systems to understand spoken and written human language, allowing the analysis, recognition, and generation of texts in natural language. ⁽¹⁾

In practice, AI has generated innovative solutions in the health field, having been used to support and accelerate patient screening and diagnosis, analyze imaging exams, predict risk, provide cognitive support, and also facilitate the intelligent search for and retrieval of relevant data, such as biomedical literature. ⁽³⁾

One of the most common applications of artificial intelligence in the medical field is the use of Expert Systems (ES), which “are programs designed to acquire and make available the operational knowledge of a human expert in a given area or field of practice.”

⁽⁴⁾

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In medicine, these systems can be used as tools to support diagnosis, prognosis, and therapeutic planning, by analyzing clinical data and presenting information or recommendations to the health professional. However, their results should not replace clinical judgment; it is up to the responsible professional to critically evaluate the information provided and make the final decision regarding patient care. ^(1,2)

In addition, there are Medical Decision Support Systems (MDSS), which are based on decision analysis principles that organize and interpret relevant information about the risks and benefits of different therapeutic alternatives. Their main purpose is to assist physicians and patients in the process of choosing the most appropriate treatment, making decision-making clearer and better founded. ⁽⁴⁾

Even so, patient autonomy remains essential, since it is up to the patient to choose the treatment after due clarification from the responsible professional, who must transparently present the implications and possible risks of each procedure. These systems have been widely used because they provide a structured way of evaluating the various options available, offering technical and analytical support. ⁽⁴⁾

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In general, MDSS can be classified into two groups: those with limited or nonexistent decision-making capacity of their own, aimed at data retrieval, calculation execution, and initial analysis of clinical information; and those equipped with automated reasoning and inference mechanisms, such as expert systems for disease classification or rule-based queries. In their composition, MDSS usually include modules aimed at patient profiling and assessment, diagnosis, and result analysis. ⁽⁴⁾

A notable example is Dr. Watson, developed by IBM, which applies deep learning techniques to identify patterns in large volumes of medical data, providing decision-making support for health professionals. ⁽²⁾

Another point worth highlighting is the evolution of *deep learning* techniques and artificial neural networks, which enable the identification of complex patterns in medical images and clinical data, contributing to the development of tools that support diagnosis and the personalization of care. Inspired by the functioning of biological neural networks, these computational structures can be trained with large datasets and, when subjected to appropriate updating and validation processes, improve their

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performance when faced with new information and different clinical contexts. ⁽¹⁾

In addition, Natural Language Processing (NLP) has established itself as an essential tool for the interaction between computational systems and health professionals, allowing the automatic analysis of medical texts, electronic health records, and scientific literature. NLP facilitates the extraction of relevant information, reducing the time required for clinical research and contributing to evidence-based decisions. ⁽¹⁾

The impact of AI in the sector also involves organizational and social transformations. The centrality of care, historically based on the physician-patient relationship, is beginning to incorporate technology as a mediator of decisions. This phenomenon may increase efficiency and accuracy, but it also raises challenges regarding patient autonomy, trust in the therapeutic relationship, and the role of the health professional as the final decision-maker. ⁽⁵⁾

Furthermore, technological evolution reinforces the need for integration among clinical knowledge, computational expertise, and ethics. Technology alone does not guarantee positive results; it is essential that its implementation take into account equity,

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inclusion, and transparency, avoiding biases in the data and ensuring that systems are aligned with the principles of justice and dignity in health care. ^(3,5)

As these technologies become more integrated into everyday clinical practice, the need to reflect on their ethical and legal impacts also grows. The use of intelligent systems in medicine involves decisions that can directly affect the life and integrity of patients, requiring transparency in algorithms, accountability for any failures, and respect for the fundamental principles of bioethics. Thus, understanding the ethical and legal implications of the use of artificial intelligence becomes indispensable to ensure that technological advancement proceeds in harmony with safety and human dignity. ⁽⁵⁾

2. Ethical and Legal Aspects

The application of artificial intelligence in health is not limited to technological advances but involves complex ethical and legal challenges. One of the central principles is equity and inclusion, which should guide the development and implementation of AI systems. Biased tools can undermine public trust, reinforcing existing inequalities in access to health care. For this reason, it is

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essential that developers carefully assess the quality and representativeness of the data used, identifying possible biases and considering the impacts of the application in different socioeconomic contexts. ⁽³⁾

Although artificial intelligence promotes efficiency, it also presents epistemic problems related to the quality and objectivity of the information produced, since algorithms depend directly on the data and programming decisions of their developers, reflecting values and conceptions about health that may be influenced by economic or cultural interests. This can generate incorrect diagnoses, especially on a large scale, affecting not only individual patients but entire groups and the distribution of resources in health institutions. ⁽⁶⁾

Another critical point concerns normative problems linked to automated decision-making in health care. The use of AI can limit the autonomy of patients and professionals, especially when there is uncritical trust in the supposed objectivity of the decisions offered by the algorithm. At multiple levels — interpersonal, group, institutional, and social — this can lead to the devaluation of the physician-patient relationship, the imposition of unjust decisions,

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or the transformation of fundamental values regarding what constitutes health care. ^(5,6)

In the legal sphere, transparency emerges as a central ethical principle. AI systems must be intelligible and explainable to health professionals, patients, and regulators, allowing for oversight and public scrutiny.

In the European Union, the General Data Protection Regulation (GDPR) ⁽⁷⁾ establishes duties to inform data subjects about the existence of automated decisions, the logic involved, and their relevance and possible consequences for the data subject. In addition, Article 22 provides for protection against decisions based exclusively on automated processing that produce legal effects or significantly affect the individual, ensuring, in certain cases, guarantees such as human intervention, the expression of the data subject's point of view, and the possibility of contesting the decision. This set of guarantees has been associated with what is known as the right to explanation of automated decisions. ⁽⁸⁾

The regulation of algorithms has become a growing concern in contemporary legal systems, being the subject of debates and formulations in different countries and international organizations. To date, there is a scarcity of binding regulatory instruments, largely

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limited to legislation aimed at the protection and privacy of personal data. In other areas, the construction of a regulatory framework is still occurring gradually, mainly through soft law instruments, such as codes of conduct, ethical guidelines, and recommendations drawn up by governmental bodies, advisory councils, research centers, and technology companies.⁽⁹⁾

In summary, the ethical and legal aspects of AI in health involve: transparency and explainability, that is, ensuring that algorithms and automated decisions are understandable and auditable; equity and inclusion, aimed at preventing biases in data and applications, promoting justice in access to health care; the autonomy of the patient and the professional, with the objective of ensuring that artificial intelligence complements, rather than replaces, human judgment; responsibility and traceability, since it is necessary to clearly define the actors responsible for automated decisions, avoiding unjust or disproportionate harm; and harmonization with human rights and legislation, so as to integrate the protection of personal data.^(5,6)

In light of these ethical and legal challenges, it is clear that the regulation of artificial intelligence in health needs to evolve to keep pace with technological advancement, ensuring that its use

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respects fundamental rights and human dignity. The need for clear regulatory structures and solid ethical principles reinforces the importance of considering different international experiences and practices, which can serve as a reference in the construction of effective and safe policies.

3. Evolution of AI Regulation in Health

3.1 International Landscape

The development and application of artificial intelligence in health has drawn increasing attention in international legal systems, given the complexity and the ethical and social risks involved. In recent years, different countries and international organizations have sought to create regulatory instruments to govern the use of AI, focusing on privacy, safety, transparency, and the protection of human rights.⁽⁹⁾

One of the main reference models is the European Union's General Data Protection Regulation (GDPR)⁽⁷⁾, in force since May 2018. This regulation, in addition to protecting personal data, established the so-called right to explanation, ensuring that individuals affected by automated decisions can understand the criteria used and contest such decisions.⁽⁸⁾

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The GDPR provides for human intervention and the opportunity to review decisions, consolidating what is known as algorithmic due process. European regulation is often cited as a global benchmark, inspiring policies and legislation in other countries, particularly with regard to transparency and accountability in the use of AI in health. ⁽⁷⁾

In addition to the GDPR, several international initiatives seek to develop ethical and technical guidelines for AI in health. Organizations such as the OECD, UNESCO, and the World Health Organization (WHO) have published recommendations on the safe, transparent, and responsible use of AI technologies. Although not binding, such guidelines offer parameters in this regard. ^(9,10)

Another important European regulatory milestone is Regulation (EU) 2024/1689, known as the Artificial Intelligence Regulation or AI Act ⁽¹¹⁾, which establishes harmonized rules for the development, placing on the market, and use of artificial intelligence systems in the European Union. The regulation adopts a risk-based approach, imposing distinct obligations according to the purpose, the context of use, and the potential impact of the system on health, safety, and fundamental rights. ⁽¹⁰⁾

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In the field of medicine, the classification of an AI system as high-risk depends on the specific characteristics of its use. Under Article 6 of the *AI Act*, systems that constitute safety components of medical devices, or that are themselves medical devices, will be considered high-risk when the product is subject to third-party conformity assessment under applicable European legislation. Thus, not every AI tool used in the health field is automatically classified as high-risk; rather, an analysis of its intended purpose, function, and the regulatory regime to which it is subject is required. ^(10,11)

The final regulation establishes that classification depends on specific criteria, including whether the product is subject to third-party conformity assessment, and not merely on the fact that the technology is used in health care. The *AI Act* entered into force on August 1, 2024, and its provisions follow a gradual timetable of application. ⁽¹¹⁾

The European Regulation classifies risks into four categories:

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Risk Level	Legal Basis	What it is	Obligations
Unacceptable Risk	Art. 5	AI practices prohibited for violating fundamental EU values	Total ban: may not be placed on the market, put into service, or used in the EU
High Risk	Arts. 6–49 + Annex III	Systems that may cause significant harm to health, safety, or fundamental rights	Mandatory requirements: risk management system, quality of training data, technical documentation, event logging, transparency to users, human oversight, accuracy/robustness/cybersecurity, conformity assessment prior to marketing
Limited Risk	Art. 50	Systems with specific transparency risks (do not cause serious	Transparency obligation: inform the person that they are interacting with an AI, or that the content was generated/manipulated by AI

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		harm, but may deceive)	
Minimal Risk	—	The vast majority of AI systems, with no relevant risk identified	No specific legal obligations: free use, with voluntary adherence to encouraged codes of conduct
Author's own elaboration, based on European Regulation 2024/1689 Considering the criteria established by the AI Act, AI-based medical support devices predominantly fall into the high-risk category, which imposes stricter requirements and obligations on developers and providers. ⁽¹⁰⁾ The purpose of the AI Regulation is to ensure that systems placed on the market are safe and comply with current legislation on fundamental rights and Union values. The high-risk classification in medicine is specifically aimed at mitigating potential biases, errors, and the lack of transparency that may arise in the clinical context. ⁽¹⁰⁾ In the United States, the Food and Drug Administration (FDA) has been driving a flexible regulatory model, focused on ensuring			
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the safety of AI-based devices, with an emphasis on iterative processes and continuous machine learning. ⁽³⁾

The regulation of AI in medicine in the United States is complex, multifaceted, and continuously evolving, involving federal laws, specific health regulations, and state tort liability laws. The central regulatory agency for the oversight of clinical AI systems is the Food and Drug Administration (FDA), which operates under the Federal Food, Drug, and Cosmetic Act (FDCA) ⁽¹²⁾. The FDCA regulates the safety and efficacy of drugs and medical devices, which includes certain clinical artificial intelligence software. ⁽³⁾

According to the FDCA's definition (21 USC § 321(h)(1)) ⁽¹²⁾, a medical device is

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is: recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or intended to affect the structure or any function of the body of humans or other animals; and which does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals,

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and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

In 2016, the 21st Century Cures Act ⁽¹³⁾ amended this definition by introducing Section 520(o), which excludes certain computer program (software) functions from the medical device category, recognizing that not every health-oriented program should be subject to the same regulatory oversight, provided they are intended to display, analyze, or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines); to support or provide recommendations to a health professional regarding the prevention, diagnosis, or treatment of a disease or condition; and to allow the health professional to independently review the basis for the recommendations presented by the software, such that it is not intended for the professional to rely primarily on those recommendations to make a clinical diagnosis or treatment decision for an individual patient. ^(13, 14)

In the case of clinical decision support systems, the exclusion applies only when the legal criteria are cumulatively met. The software's function may not be intended to acquire, process, or analyze medical images, signals from in vitro diagnostic devices, or

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patterns from signal acquisition systems. In addition, it must be intended to display, analyze, or present medical information; to support or provide recommendations to a health professional regarding prevention, diagnosis, or treatment; and to allow that professional to independently examine the basis for the recommendation, such that it does not predominantly depend on it to formulate a diagnosis or make an individual therapeutic decision.⁽¹⁴⁾

The FDA classifies medical devices into three categories: Class I, considered low risk to users; Class II, moderate risk; and Class III, considered high risk to users.^(12,14)

This understanding was detailed in the document “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)”⁽¹⁵⁾, published by the FDA in 2019, which outlines the guiding principles for the oversight of these systems.⁽¹⁴⁾

This approach was later developed through more specific documents and guidance. In the current final guidance on Predetermined Change Control Plans (PCCPs)⁽¹⁶⁾, published in August 2025, the FDA recommends that the manufacturer describe

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in advance the planned modifications to the device, the methodology to be used to develop, validate, and implement such changes, and the assessment of their possible impacts. When the PCCP is reviewed and authorized as part of a regulatory submission under the 510(k), *De Novo*, or PMA procedures, the modifications covered by the plan may be implemented without a new individual submission, provided they remain within the authorized limits and the safety and efficacy of the device are preserved (FDA, 2025). The guidance document further clarifies that these guidelines constitute non-binding recommendations, reflecting the agency's current understanding of the subject. This approach demonstrates the U.S. regulatory effort to balance technological innovation and safety, while at the same time posing the challenge of keeping pace with the rapid evolution of machine learning algorithms and their ethical and legal implications for health care. ⁽¹⁶⁾

The U.S. regulatory approach also considers the product's total life cycle, encompassing development, validation, transparency, bias prevention, performance monitoring, and post-market update management. With regard to clinical decision support systems, FDA guidance seeks to differentiate software functions excluded from the legal definition of a medical device from those that remain

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subject to regulatory oversight, particularly according to the health professional's ability to independently review the basis for the recommendations presented by the system. ^(3,16)

A relevant challenge is the explainability of AI tools, since many deep learning-based systems function as “black boxes,” making it difficult to ensure transparency in the decision-making criteria. U.S. regulators consider that a lack of explanation may compromise trust, accountability, and post-market monitoring of these technologies. ^(3,14)

Another challenge faced by the United States is the interoperability of health systems. The integration of artificial intelligence software with different clinical platforms and databases requires uniform technical and regulatory standards capable of ensuring secure and effective communication between systems. The FDA collaborates with other institutions, such as the Federal Trade Commission (FTC) and the National Institute of Standards and Technology (NIST), in formulating technical standards and best practices for the ethical and safe use of algorithms. ^(3,13,15)

The privacy of patient data and the representativeness of the datasets used to train AI systems are other important obstacles.

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HIPAA provides a minimum floor of protection for health information in the United States, but its scope is limited. This creates regulatory gaps, especially when data comes from non-traditional sources or sources not covered by HIPAA. ⁽¹⁴⁾

It should also be noted that tort liability in U.S. states is still not fully adapted to AI technologies in health care. The intersection between FDA regulatory approval and state liability actions creates uncertainty as to who should be held accountable when AI systems cause harm. There are tensions between federal oversight and state litigation. ^(3, 14)

In summary, in the United States, the regulation of AI in health presents a significant regulatory framework centered on safety, efficacy, privacy, and accountability, but faces challenges such as the rapid evolution of technology, the need for algorithmic transparency, the use of large-scale data, and the adaptation of the tort liability system. Current regulatory practices are important but still require improvement to keep pace with innovation in the sector.

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3.2 Brazilian Regulation

Although less advanced, Brazil has begun discussions on guidelines for the responsible use of AI in health, aligning itself with international recommendations and seeking to promote safe and transparent access, particularly in digital health public policies. This movement was driven by national science and technology policies, such as Ordinance No. 1,122, of March 19, 2020 ⁽¹⁷⁾, issued by the then Ministry of Science, Technology, Innovations, and Communications (MCTIC), which included artificial intelligence among the “Enabling Technologies” prioritized for the country's scientific and technological development for the 2020–2023 period. This recognition reinforced the importance of AI as a strategic tool for innovation and for the improvement of public services, including the health sector.

At the national level, the Brazilian Artificial Intelligence Strategy (EBIA) ⁽¹⁸⁾, established by the Ministry of Science, Technology, and Innovations (MCTI) in 2021, represents an important milestone in this debate. The EBIA is structured around thematic axes, the first of which is legislation, regulation, and ethical use, of a cross-cutting nature. This axis recognizes the need to balance the protection and safeguarding of individual rights, the

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creation of structures that encourage technological development, and the establishment of legal parameters capable of providing legal certainty to the various actors involved in the value chain of autonomous systems.

This approach seeks to promote responsible innovation without disregarding the potential ethical, social, and legal risks inherent in the use of AI in health.

The landscape of technology adoption also reveals relevant aspects, since Brazil stands out in relation to Europe with regard to the number of companies that use AI for workflow automation, followed by applications in image recognition and processing, a trend that is particularly significant for the health sector, where diagnoses based on medical images are increasingly common. In other types of use, the differences between Brazilian and European companies are small, although in Europe there is a more homogeneous distribution among the different types of applications, indicating a more balanced technological maturity.⁽¹⁹⁾

In the legal field, the regulation of artificial intelligence in health is closely linked to the General Personal Data Protection Law (LGPD — Law No. 13,709/2018)⁽²⁰⁾, enacted in August 2018 and in force since September 2020, with administrative sanctions

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applicable as of August 2021. Although the LGPD does not explicitly mention “artificial intelligence” or “algorithm,” the law establishes principles and rights that directly impact the application of AI in health, such as transparency, the explanation of automated decisions, and the possibility of reviewing such decisions. ⁽⁹⁾

These foundations are compatible with international ethical and regulatory principles and constitute the basis for future AI regulation in the country, particularly in the field of health, where the handling of sensitive data requires a high level of security and accountability. ⁽⁶⁾

In addition, the protection of trade and industrial secrets must be weighed together with the right to explanation. Brazilian legislation provides for audits in cases of suspected discrimination, balancing business interests and individual rights, reinforcing the need for harmonization between technological innovation and human rights. ⁽⁹⁾

Article 20 of the LGPD ⁽²⁰⁾ guarantees data subjects the right to request the review of decisions made solely on the basis of automated processing of personal data that affect their interests. Unlike the European GDPR, Brazilian law does not provide for a mandatory obligation of automatic human intervention, nor the

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right not to be subject to exclusively automated decisions. The original wording provided for the review to be carried out by a “natural person,” but this provision was amended by a provisional measure and subsequently consolidated into law, allowing future regulations to define the need for human oversight. ⁽⁹⁾

This legislative openness creates room for policies such as the EBIA and infra-legal regulations to establish additional requirements for explainability and auditing in critical applications, such as those in health care. ^(9,18)

Although the LGPD focuses primarily on the protection of personal data, it has important implications for AI in health, especially with regard to algorithmic transparency. The law ensures that anyone affected by automated decisions has access to clear information about the criteria and procedures used, promoting intelligible explanations and enabling the contestation of results. This mechanism is connected to the ethical principle of transparency, considered fundamental in the use of AI in health contexts, since it allows patients, professionals, and regulators to understand how the systems actually work. ^(9,20)

This guideline is consistent with the EBIA's emphasis on the responsible governance of AI systems, which includes mechanisms

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for accountability, monitoring, and continuous auditing of algorithms used in sensitive sectors. ^(6,18)

Beyond the LGPD, Brazil is still at an early stage in the development of specific regulations for artificial intelligence in health. The current approach combines soft law — through codes of conduct, professional council guidelines, recommendations from public bodies, and regulations from research institutes — with the systematic interpretation of the LGPD, the Federal Constitution, and the Consumer Protection Code. These measures aim to balance the right to explanation and review with the protection of trade and industrial secrets, which are essential for the development of AI-based business models. ^(6,9)

Brazilian regulation also seeks to prevent discrimination and injustice arising from automated decisions. Studies indicate that the growing inclusion of AI in clinical and administrative decisions can generate normative and epistemic problems, affecting patient autonomy, the physician-patient relationship, and the distribution of health resources. ^(5,6)

For this reason, the legislation emphasizes the need for audits and review mechanisms, especially in cases of suspected discrimination or harm to fundamental rights. ^(9,18,20)

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This concern reflects a movement toward alignment with international AI governance practices, although Brazil still lacks robust regulatory instruments detailing specific obligations for the health sector. ⁽⁶⁾

In summary, although Brazil does not yet have a specific regulatory framework for AI in health, the LGPD establishes important foundations that guide the ethical, transparent, and responsible use of these technologies. The development of infra-legal regulations and future specific standards will be essential to consolidate rights such as explainability, review of automated decisions, traceability, and accountability, aligning the use of AI with ethical principles and human rights. ^(6,9)

The inclusion of AI among the strategic priorities for science and technology (Ordinance No. 1,122/2020) and the creation of the EBIA (Ordinance No. 4,617/2021) represent significant institutional milestones in this process. Both reinforce the Brazilian State's intention to develop an ecosystem of responsible innovation, balancing the encouragement of research with the protection of rights. This trajectory shows that the country has been building a regulatory path that, although still incipient, seeks to converge with

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international regulatory benchmarks and strengthen legal certainty in the use of AI in health. ^(17,18)

4. Conclusion

The regulation of artificial intelligence (AI) in health is an essential and emerging topic worldwide, facing the challenge of keeping pace with algorithms that, unlike traditional medical devices, are in constant change and learning. This technical complexity requires a delicate balance between encouraging technological innovation and ensuring that the use of these tools invariably results in benefits for human beings, respecting safety and fundamental rights. ^(9,10)

In Brazil, the initial milestone of this debate is the General Personal Data Protection Law (LGPD — Law No. 13,709/2018), which, although it does not explicitly mention “AI,” establishes principles of transparency and the right to explanation and review of automated decisions. ⁽⁹⁾ Article 20 of the LGPD guarantees data subjects the right to request the review of decisions made solely on the basis of automated processing of data that affect their interests. In addition, the Brazilian Artificial Intelligence Strategy (EBIA), established in 2021, is structured around axes such as “legislation,

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regulation, and ethical use,” seeking to balance the safeguarding of individual rights with the creation of legal parameters that provide legal certainty. In addition, MCTIC Ordinance No. 1,122/2020 included AI among the priority “Enabling Technologies” for the country's strategic development. ^(17,18)

Internationally, the European Union established a global benchmark with the Artificial Intelligence Regulation (AI Act), which adopts an approach based on four risk levels ⁽¹⁰⁾: minimal, limited, high, and unacceptable. AI systems intended for medical diagnosis are classified as high-risk, requiring strict compliance with ethical and safety standards given their potential impact on human life. ⁽¹⁰⁾

In the United States, central oversight rests with the FDA, which operates under the Federal Food, Drug, and Cosmetic Act (FDCA) to ensure the safety and efficacy of clinical software. The 21st Century Cures Act of 2016 detailed criteria for certain clinical decision support software to be excluded from the definition of a medical device, provided it allows the health professional to independently review the basis for the recommendations presented. More recently, the FDA's August 2025 guidance on Predetermined Change Control Plans (PCCPs) allowed manufacturers to implement

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planned iterative modifications without the need for new individual submissions, provided that safety and efficacy are preserved. ^(14,16)

In summary, the safe advancement of AI in health depends on building a robust ethical and regulatory framework that ensures algorithmic explainability and transparency. Transparency is regarded as the key principle indispensable for other rights, such as patient autonomy and civil liability, to be effectively realized. The consolidation of responsible governance practices and the continuous monitoring of the product life cycle will be crucial for technology to effectively contribute to health, strengthening the trust of professionals and patients in the care system.

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