CIVIL LIABILITY IN AI DIAGNOSTIC ANALYSIS: THEORIES AND REGULATORY CHALLENGES

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Abstract: The aim of this article is to raise thoughts about possible adaptations to the classic theories of civil liability applied to health, in the face of the use of medical devices with Artificial Intelligence (AI). The article seeks to situate readers in relevant aspects of the topic and to help with a general understanding of the proposed issue. The results of the study indicate the problem of the emerging behavior of machines, as well as the lack of definition of what would be the diligence expected of a doctor in the context of diagnostic analysis. It is argued that it is unreasonable to compare the data processing capacity of an artificial intelligence with the ability of a human doctor in the investigation of guilt. The final considerations reveal some changes in the interpretation of the assumptions of civil liability.

Keywords: civil liability; artificial intelligence; diagnostic analysis.

INTRODUCTION

Artificial intelligence, or simply AI, has not only revolutionized the areas of knowledge dedicated to the development of technology. Like any fact capable of impacting legal relations, the advent of AI and its machine learning models has led to significant changes in the business models of Brazilian law and has caused doubts as to the division of responsibilities when damage occurs as a result of its use.

Smart contracts, cryptocurrencies, digital platforms, diagnostic analysis algorithms and robot surgeons are all examples of the revolution brought about by AI, the legal impact of which will be discussed in the light of civil liability. However, due to the thematic delimitation assumed by this study, the focus will be on the liability regime for the use of artificial intelligence in the health area, especially diagnostic analysis.

A relevant example of the application of AI in diagnostic analysis comes from Oxford University's John Radcliffe Hospital, where an intelligent device has been developed that uses machine learning techniques to help diagnose coronary heart disease. This software has demonstrated a diagnostic accuracy rate of around 90%, surpassing the average accuracy rate of 80% achieved by doctors[1].

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[1] Gillespie, Stuart. *The Oxford spinout company using AI to diagnose heart disease*. 2018. Available at: <https://www.research.ox.ac.uk/Article/2018-10-15-the-oxford-spinout-

Another example is IBM's "Watson for Oncology"[2]. The aim of "Watson for Oncology" is to help doctors and health professionals make decisions related to the diagnosis and treatment of cancer patients, providing recommendations based on a wide range of health data and scientific literature.

Brazilian initiatives include the creation of the Laura Robot by Jacson Fressatto. This technology plays a key role in assisting medical and nursing teams in risk management, providing early detection of critical conditions and enabling timely interventions, which results in an improvement in the quality of care provided[3].

Another initiative is the startup Onkos Diagnósticos Moleculares, created at the Supera Innovation and Technology Park in Ribeirão Preto - SP. Its mechanism is to carry out a genetic test, mirTHYpe, to improve the classification of indeterminate thyroid nodules to determine whether the lesion is benign or malignant, using artificial intelligence.

It can therefore be seen that artificial intelligence plays a significant role in healthcare, providing support for clinical decision-making. These programs have the ability to process and analyze large volumes of data quickly and efficiently. The integration of artificial intelligence with specialized medical knowledge presents promising potential for more assertive diagnoses and personalized treatment. It is important to emphasize that the aim is not to replace healthcare professionals with AI systems, but rather to recognize the potential benefits of this new technology in helping professionals make decisions.

Among the many possible benefits is the speed with which artificial intelligence software can obtain diagnoses, which can be crucial for the immediate start of treatment and the subsequent recovery of the patient, especially in cases of rapidly progressing diseases or urgent and emergency situations.

However, it is important to mention that these potential benefits are accompanied by relevant ethical and legal issues, which need to be discussed in the following sections in the light of civil liability.

company-using-ai-to-diagnose-heart-disease> [Accessed 24 Jun. 2023].

[2] IBM. Manual, IBM Japan Sales. *IBM Watson for Oncology SaaS (5725-W51).* 2022. Available at: <https://www.ibm.com/common/ssi/ShowDoc.wss?docURL=/common/ssi/rep_sm/1/760/ENUS5725-W51/index.html> [Accessed 26 Jun. 2023].

[3] Silva, Rodrigo da Guia, and Rafaella Nogaroli. Inteligência artificial na análise diagnóstica: benefícios, riscos e responsabilidade do médico. In: *Debates Contemporâneos em Direito Médico e da Saúde*. São Paulo: Revista dos Tribunais, 2020.

I. THEORIES OF CIVIL LIABILITY IN BRAZILIAN LAW APPLIED TO HEALTH

A. Initial considerations

In the context of healthcare, the analysis of civil liability is a challenge. In order to identify the cause of the damage and the party responsible for the duty to compensate, it is necessary to consider the possible parties involved, such as the patient, the doctor, the healthcare establishment and the manufacturer.

With the inclusion of artificial intelligence as a "fifth character", the analysis becomes even more complex. However, before inserting AI into this study, it is appropriate to review the main theories of civil liability applied to relationships developed in the health area.

B. Hospital strict liability

The damages that a patient can suffer will be presented in two large groups: a) damages resulting from medical error and investigated in the light of the subjective responsibility of the liberal professional; b) damages suffered as a result of the hospital structure attributed as objective responsibility.

The hospital is objectively liable, for example, for the acts of its employees, equipment failure, hospitality, hospital infection, i.e. services related to the business establishment itself, under the regime of art. 14 of the Consumer Protection Code (CDC).

With regard to damage caused by a medical act and occurring within the hospital, even though the hospital is objectively liable, the duty to compensate only arises if the doctor's fault is proven. Thus, the doctor and the hospital are jointly and severally liable[4].

It is worth remembering that the Superior Court of Justice (STJ) considers that public hospitals and health posts are not subject to the rules of the CDC - REsp 1.187.456: "when the public service is provided directly by the state and funded by tax revenue, it is not a consumer relationship and the rules of the Consumer Protection Code do not apply"[5].

Having recalled these initial definitions, the point of convergence between the classic theories of civil liability applied to healthcare

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[4] Farias, Cristiano Chaves de; Rosenvald, Nelson; Braga Netto, Felipe. *Curso de Direito Civil: responsabilidade civil*. 10th ed. São Paulo: Juspodivm, 2023.

[5] Brasil. Superior Tribunal de Justiça. *Recurso Especial No. 1.187.456 - DF*. Recorrente: Estado do Rio de Janeiro. Recorrido: João Cruz e outro. Relator: Ministro Castro Meira. Diário Oficial da União, Brasília, DF, 16 Nov. 2010.

establishments and the new contours that this liability takes on with the insertion of AI-equipped medical devices in their activity will be presented below.

C. Subjective liability of Medical Doctors

Article 951 of the Civil Code establishes the duty to compensate those who, in the exercise of their profession, act with negligence, recklessness or malpractice, cause the patient's death, aggravate their condition, cause them injury, or render them unfit for work.

Although it is no legal innovation to talk about the institutes of negligence, recklessness and malpractice, it is worth recalling some important basic aspects so that it is possible to advance in understanding and insert the fifth character in this relationship - artificial intelligence - in the next section.

Negligence has at least two relevant contours: the first concerns the lack of attention and diligence expected of the doctor: when he fails to order essential tests to investigate the disease or prescribes medication without assessing the patient's individual conditions, such as allergies and the possibility of harmful drug interaction. The second concerns a gross error, such as forgetting gases inside a patient undergoing surgery. In this case, guilt results from the circumstances and does not need to be demonstrated, as there was a lack of a basic duty of care[6].

It would be difficult to investigate the doctor's responsibility if it weren't for the subjective nature of the responsibility, given that the medical act depends, to a certain degree, on the patient's response. Each organism has an immunological response, the medication prescribed for one may not have the same response as for another, in surgery an adverse effect may manifest itself in one patient and not in another, regardless of the medical technique applied.

Another relevant aspect of the investigation of medical fault that will serve as the basis for the discussion in the following sections is diagnostic error. Not every diagnostic error generates the duty to indemnify. Firstly, there must be a causal link between the error and the possible damage. Secondly, the error must be culpable.

Under normal conditions, without the assistance of intelligent software, a doctor who is faced with two or more therapeutic paths and prescribes one that will cause harm to the patient, can be held responsible for the worst choice, as long as the error in technical conduct is proven.

To constitute a diagnostic error, there should be proof that there was evidence that the treatment chosen was not recommended. On the other hand,

[6] Farias, Cristiano Chaves de; Rosenvald, Nelson; Braga Netto, Felipe. *Curso de Direito Civil: responsabilidade civil*. 10th ed. São Paulo: Juspodivm, 2023.

if the medical literature is controversial and presents multiple viable therapies, including the one chosen by the doctor (even if it causes harmful adverse effects), this does not constitute a diagnostic error.

However, fault for misdiagnosis will be established if the doctor failed to use all the resources available to investigate the disease, with fault being excluded only if it is shown that due to the lack or absence of technical conditions he was unable to act otherwise - which can be exemplified by the patient who arrives at a public hospital with severe headaches but the CT machine is broken and so it is not identified that he is suffering from a stroke.

As Cristiano Chaves, Nelson Rosenvald and Felipe Braga Netto point out:

> Medicine is not a science that can be solved using equations. It's not about knowing only one answer. If the solution to a given health problem is controversial even among doctors, how can we (reasonably) hold the doctor responsible for opting for one solution and not another?[7]

It can therefore be seen that the investigation of medical fault is already complex due to all the elements and variants listed above. If we live with controversies and volatile interpretations on the subject of diagnostic error, outlining criteria for civil liability in diagnostic analysis using AI means that we are facing an even more challenging task.

But before intersecting the classical theories with the debates on responsibility in the use of AI, let's review some more important doctrinal aspects.

D. Theory of the loss of a chance in medical activity

The loss of a chance can be understood as the situation in which an agent (doctor) destroys a reasonable and real chance (cure or survival) (scientific probability) for someone (patient). In the light of medical civil liability, the STJ (REsp 1.335.622)[8] has understood the chance of cure or survival as a legally protected asset and, if it is deprived, it becomes an indemnifiable damage for the loss of a chance. This definition gains relevance in the context of medical liability in the use of AI because it gives more weight to the professional's correct decision regarding the proposed diagnosis or treatment.

As mentioned in the article's introduction, there is already software capable of delivering more accurate diagnoses and personalized treatment

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[7] Farias, Cristiano Chaves de; Rosenvald, Nelson; Braga Netto, Felipe. *Curso de Direito Civil: responsabilidade civil*. 10th ed. São Paulo: Juspodivm, 2023.

[8] Brasil. Superior Tribunal de Justiça. *Recurso Especial No. 1.335.622 - DF (2012/0041973-0).* Recorrente: Alberdan Nascimento de Araújo. Advogado: Jose Emiliano Paes Landim Neto. Recorrido: Hospital Santa Lúcia S/A. Advogado: Roberto de Souza Moscoso. Relator: Ministro Ricardo Villas Bôas Cueva. Brasília, DF, 18 Dec. 2012.

plans with a high accuracy rate. However, even if these systems have advisory characteristics and not decision substitution, if a diagnostic error occurs due to an AI-supported decision, can medical guilt be assessed by the same criteria as before? This is what the last section of this article sets out to answer.

II. CIVIL LIABILITY IN THE USE OF ARTIFICIAL INTELLIGENCE: BRIEF COMMENTS ON THEORETICAL AND REGULATORY CONSTRUCTS

A. European Union directives and proposed regulations

In the current scenario of regulating artificial intelligence, the European Union is notoriously the most advanced in the debate. Some of its initiatives stand out and will be discussed in the next few lines.

The 2019 Ethics Guidelines for Trustworthy AI[9] was not the first EU initiative on the subject, but it did fill in the gaps in Resolution 2015/2103 (INL) on the subject of civil liability, since at the time the proposal's formulators felt that the institutes of law were insufficient to regulate the matter.

For its part, the 2019 document aimed to guide the development and use of AI in Europe and made significant contributions with the election of seven ethical principles: (I) Transparency; (II) Non-discrimination; (III) Responsibility; (IV) Reliability; (V) Privacy; (VI) Solidarity; and (VII) Respect for human dignity.

In 2020, the White Paper on Artificial Intelligence: a European approach to excellence and trust[10] was published. Its thematic focus was the development of ethical and safe AI, listing proposals such as the creation of a regulatory framework for AI with a focus on transparency, accountability and privacy, with the protection of the individual in mind.

The document addressed the regulatory challenges of AI and made significant progress in the area of civil liability by listing three different lines of action: (I) General safety obligation; (II) Future adaptation of producer liability; and (III) The need to find forms of liability that respond to the problems posed by AI entities, while also proposing an adaptation of the European legislative framework.

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[9] European Commission. *Ethics Guidelines for Trustworthy AI: High-Level Expert Group on Artificial Intelligence*. Brussels, 08 Apr. 2019. Available at: <https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=60419> [Accessed 28 Jun. 2023].

[10] European Commission. *White Paper on Artificial Intelligence*. Brussels, 19 Feb. 2020. Available at: <https://commission.europa.eu/system/files/2020-02/commission-white-paper-artificial-intelligence-feb2020_en.pdf> [Accessed 28 Jun. 2023].

Also in 2020, the European Parliament presented a Resolution 2020/2014 (INL)[11] containing recommendations to the European Commission regarding the civil liability regime applicable to AI. Among the conclusions, three main aspects are worth highlighting.

Firstly, it was stressed that there was no need for a complete overhaul of existing civil liability rules. Next, they recognized the importance of analyzing the typology of AI in order to define the applicable civil liability regime, taking into account the different risks involved in different AI systems. In addition, they rejected, at least for the moment, the idea of creating a separate legal personality for AI-driven systems.

In addition, the Resolution introduced a risk classification for AI, establishing criteria for considering an AI system as high risk. These criteria include: (I) the application being used in sectors in which, due to the characteristics of the activities typically carried out, significant risks can be expected, such as the medical field; and (II) the application being used in a way that makes the occurrence of significant risks likely.

In June 2023, the European Union approved the text of the Artificial Intelligence Regulation (EU AI Act)[12] guided by criteria such as safety, transparency, traceability, non-discrimination and respect for the environment, mentioning that medical devices will be part of the high-risk classification and generative AI, such as ChatGPT, will have to meet transparency requirements.

The text of the EU AI Act was concerned with banning the use of AI in applications with controversial contours such as emotion recognition, real-time biometrics and predictive policing in public spaces, a ban on social scoring and new restrictions on recommendation algorithms on social networks.

This regulatory initiative is clearly the one that has made the most progress on the international scene in this area, but it is not the only one. The regulations of the United States and the United Kingdom are also worthy of mention, but due to the objective nature of this article, they will not be the subject of study.

B. Brazilian regulatory scenario

As mentioned in the article's introduction, Brazil already has initiatives

[11] European Commission. *Resolução 2020/2014 (Inl)*. Brussels, 20 Oct. 2020. Available at: <https://www.europarl.europa.eu/doceo/document/TA-9-2020-0276_PT.html> [Accessed 27 Jun. 2023].

[12] European Commission. *Artificial Intelligence Act*. Strasbourg, 14 Jun. 2023. Available at: <https://www.europarl.europa.eu/doceo/document/TA-9-2023-06-14_EN.html> [Accessed 26 Jun. 2023].

to develop AI systems, such as the medical device startups Robô Laura and Onkos Diagnósticos Moleculares, and in terms of regulation, the discussion is centered on the recent Bill of Law No. 2338 of 2023, the origin of which was the Report of the Commission of Jurists responsible for subsidizing the drafting of a substitute on artificial intelligence in Brazil, a substitute proposal for Bill of Law No. 21/2020 by Congressman Eduardo Bismarck (PDT-CE).

Initially, there were three bills on artificial intelligence, which were later brought together - Bill No. 21/2020 (encompassing bills No. 5,051/2019 and No. 872/2021). The initiative was principled and included debates on governance, but also included a controversial point on the application of a subjective liability regime, which sparked criticism and opened the way for the Senate Committee of Jurists to re-discuss the matter. During twelve panels and an international seminar, concepts, classifications, rights, duties, impacts, governance and oversight, among others, were discussed.

With regard to civil liability, the Senate Committee of Jurists expressed criticism and opposition to regulating damage caused by AI systems. They argued against the immediate creation of a specific rule for this purpose. However, the Commission recognized the importance of establishing parameters that would offer greater legal certainty on the subject. The text establishes that the liability regime will be determined on the basis of the subject and the type of artificial intelligence.

In short, the liability regime will depend on the type of artificial intelligence system. For AI systems classified as (I) high risk or excessive risk, the regime of objective civil liability without solidarity will apply. For AI systems that do not fall into this category (II), subjective liability will apply, with a presumption of guilt and a reversal of the burden of proof in favor of the victim.

However, a more appropriate classification would be to follow the pillars suggested by Leonardo Parentoni[13] in terms of the purpose for which each system is used. According to this guideline, this is because accuracy, transparency and risk prevention vary significantly based on the specific purpose for which the AI system is used, as well as the way in which it is provided.

According to Felipe Medon[14], who was part of the committee of jurists:

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[13] Parentoni, Leonardo. *What Should We Reasonably Expect from Artificial Intelligence?* SSRN Electronic Journal (2022). Available at: https://www.ssrn.com/abstract=4162871 [Accessed June 24, 2023]. DOI: 10.2139/ssrn.4162871.

[14] Medon, Filipe. O anteprojeto de Marco Legal da Inteligência Artificial elaborado pela Comissão de Juristas do Senado Federal e os impactos para o Direito Médico. *Migalhas de Responsabilidade Civil.* 2022. Available at: <https://www.migalhas.com.br/coluna/migalhas-de-responsabilidade-civil/378241/o-anteprojeto-de-marco-legal-da-inteligencia-artificial> [Accessed 28 Jun. 2023].

the draft law on AI in Brazil opted for a regulation with a more restricted scope, since it left out, for example, non-professional users of AI, the state - whose liability regime is based on the Constitution - as well as the suppliers provided for by the CDC, even if they are liberal professionals.

Despite the progress made on the matter, Bill 2338 of 2023 still arouses criticism and the fear that an already obsolete regulation will be born, as it doesn't address issues that are widely debated in the scientific community, such as the problem of the opacity of algorithmic decisions, foundation models or the production of texts and videos by generative AI systems[15], as in the case of ChatGPT, Llama, Bard, etc.

On November 27, 2023, Senator Marcos Pontes (PL-SP), vice-president of the Internal Temporary Commission on Artificial Intelligence in Brazil, presented a substitute to Bill 2338/2023. This substitute has been criticized by legal experts, holding up the debate on the regulation of Artificial Intelligence in the country.

C. Some theoretical constructions on civil liability in the use of AI

There are many contributions from researchers who propose to study the subject of civil liability in the use of artificial intelligence. However, the bibliography on the subject is already too extensive to be quoted in full here, which is why we have chosen to select the authors Cintia Rosa Pereira de Lima and Mafalda Miranda Barbosa.

Cíntia Rosa Pereira de Lima[16], in her book "*Sistema de Responsabilidade Civil para Carros Autônomos*", presents a detailed analysis of the different civil liability regimes, differentiating between cases in which there is a consumer relationship and those in which there is not.

It emphasizes that it is appropriate to apply subjective liability in judging the damage between those involved in the production of the technology - despite its difficult identification. It suggests a specific addition to the Civil Code on damage caused by machines or artificial intelligence, or the creation of a specific law.

As for the damage caused by artificial intelligence in the context of consumer relations, he defends the application of the objective theory, based on product liability. On the other hand, it recognizes the reasonableness of applying exclusions of unlawfulness, among them, the emergent behavior of the machine as an external fortuitous event.

Agreeing with the author, the great challenge for modern doctrine on civil

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[15] Generative AI is a type of artificial intelligence that learns from a large amount of information and uses this learning to create something new and similar when prompted.

[16] Lima, Cíntia Rosa Pereira de. *Sistema de Responsabilidade Civil para Carros Autônomos*. Indaiatuba: Editora Foco, 2023.

liability is how damages arising from the emergent behavior of machines will be analyzed. Emergent behavior refers, for example, to the hypothesis in which the machine has been programmed to suggest chemotherapy or radiotherapy for cancer treatment and the algorithm does not choose either of these two alternatives, but rather suggests a type of cancer treatment with a low recommendation in the scientific literature.

Another point that deserves to be highlighted among scholars is how to allocate the traditional assumptions of subjective civil liability - conduct, damage, causation. Artificial intelligence impacts the analysis of conduct, as opposed to culpable action or omission, given that in addition to the behavior emerging from AI, there are many participants in the manufacturing/programming process, which makes it difficult to investigate who has incurred in negligence, recklessness, malpractice.

Another prerequisite, the causal link, would have to go into the expertise of a complex chain of algorithmic decisions to demonstrate the relationship between the machine's behavior and the damage caused to the patient. However, the cost of time and resources for such an investigation represents a real obstacle for the patient hoping for redress, as well as being a Herculean burden of proof for doctors, healthcare establishments and developers.

In addition, among the Brazilian researchers dedicated to the impacts of civil liability for the use of AI in the medical field, we have the work of Rafaella Nogaroli and Miguel Kfouri Neto[17], which will be discussed in the next topic.

In the European scenario, Mafalda Miranda Barbosa[18] states that investigating guilt in the context of the use of AI is a complex and even imprecise scenario, given that we would enter into debates such as: in the face of the guilt of the software developer, in the event of a system update carried out by a person other than the original and in the event of a system error, would the algorithm developer still be responsible? Moreover, would it be possible to identify whether the error in the algorithm's operation was due to the initial programming or to the modifications made by the system updates? These are investigations that could be impossible to prove.

A critical analysis of the contributions by authors such as Cintia Rosa Pereira de Lima and Mafalda Miranda Barbosa reveals a scenario in which civil liability, in the context of artificial intelligence in health, faces an innovative and complex dilemma. The dichotomy between subjective and objective liability, as outlined by Cintia Rosa, highlights a fundamental tension between technological advances and the maintenance of traditional

[17] Kfouri Neto, Miguel, and Rafaella Nogaroli (ed.). *Debates contemporâneos em direito médico e da saúde*. São Paulo: Thomson Reuters Brasil, 2020.

[18] Barbosa, Mafalda Miranda. *Inteligência Artificial: entre a utopia e a distopia, alguns problemas jurídicos*. Coimbra: Gestlegal, 2021.

legal principles.

While adapting the assumptions of civil liability to the age of AI is necessary, the issue of the emerging behavior of machines challenges the direct application of these elements. This behavior not only questions the practice of assigning liability based on fallible human actions, but also raises concerns about the ability to adequately track and understand algorithmic decisions.

The problem of causation in scenarios where AI plays a crucial role highlights a particularly worrying area. The burden of proof, which falls on healthcare professionals, establishments or developers, can become disproportionately onerous, given the complexity of the technologies involved. Not only does this complicate the burden of proof, but it can also inhibit responsible innovation if developers fear regulatory uncertainty or the legal consequences of unpredictable failures.

So while AI promises to transform healthcare, bringing significant potential benefits, it also imposes the need for a rethinking of existing legal paradigms in the So while AI promises to transform healthcare, bringing significant potential benefits, it also imposes the need for a rethinking of existing legal paradigms in the area of civil liability. This new paradigm must balance technological innovation with the protection of patients' rights, ensuring that civil liability continues to serve as an effective mechanism for accountability in this scenario that is beneficial to improving healthcare, but which is not without risks.

III. CHALLENGES OF CIVIL LIABILITY FOR THE USE OF AI IN HEALTHCARE

The entire literature review carried out so far has aimed to clarify in the reader's mind the most relevant aspects in the debate on civil liability in the health area, as well as explaining the regulatory initiatives and theoretical understanding on the subject of civil liability and artificial intelligence in the international and Brazilian scenarios, so that it is possible to make an intersection of knowledge to achieve the objective of this study: to raise reflections on the possible adaptations in the classic theories of civil liability in the scenario of the use of medical devices equipped with AI.

In order to understand the legal repercussions of the theories and proposals for regulation set out in the previous topic, it is first important to know how countries like the United States deal with the issue of civil liability for the use of medical devices equipped with artificial intelligence, in order to arrive at the current understanding of the Brazilian legal system.

In the US courts, the most emblematic cases involving civil liability for the use of artificial intelligence in healthcare are related to robotic surgeries. Although this is not the type of application chosen for this article, they will

be cited for the purposes of understanding the subject.

In 2016, the case of Zarick v. Intuitive Surgical was tried before the Civil Jury of the California State Court. The case discussed the civil liability of the manufacturer of the da Vinci robot in relation to the damages suffered by a patient during a robotic hysterectomy surgery. The patient, Michelle Zarick, had undergone a robotic-assisted hysterectomy in 2009. She suffered an internal burn due to a defect in the robotic equipment, which had microcracks that caused its electrical insulation to fail, which ended up allowing the electric current to reach organs outside the operative field[19].

Zarick suffered serious complications and had to undergo a laporotomy because a massive infection was found with cysts and adhesions encapsulating the ovaries and fallopian tubes, causing these organs to be removed. She also suffered damage in the region of the previous operation, as the infection spread to the vaginal cuff sewn during the robotic hysterectomy, causing it to rupture, which led to the condition that brought Zarick to hospital, the evisceration of the small intestine. The necrotic tissue and infected tissue were removed and she underwent long weeks of recovery.

Zarick's lawyer held the manufacturer responsible for the product's defect, exempting the doctor from any possible liability on the grounds that the fault was not identifiable during surgery. The thesis defended stressed that the device relied on the use of monopolar energy to cut, burn and cauterize tissue, while safer methods were already available on the market, that the manufacturer failed in pre-clinical research into the safety of using monopolar current and isolation, and that it was prioritizing profit over patient safety. After three days of deliberations, the parties reached a million-dollar settlement, ending the case with a confidentiality clause on its terms.

A Brazilian case, judged in the 4th Civil Court of the District of Florianópolis-SC, was the first to gain repercussions in the field. The case involved a patient who underwent robotic surgery to remove a kidney tumor at the Albert Einstein Hospital. Although the surgery was uneventful, in the post-operative period he began to feel severe abdominal pain and had to be hospitalized, when a bacterium called "*Burkholderia cepacia complex*" was detected. The case was diagnosed as a hospital infection caused by the fact that the robot used in the surgery had not been properly sterilized, transmitting the bacteria to the patient.

The first case leads to the conclusion that the manufacturer is liable for the product defect and the second, that the hospital is objectively liable for the condition of its facilities and equipment, which should guarantee the safety expected by the patient, a legal scenario that can be resolved under the Consumer Protection Code. However, when it comes to AI-supported

[19] Kfouri Neto, Miguel, and Rafaella Nogaroli (ed.). *Debates contemporâneos em direito médico e da saúde*. São Paulo: Thomson Reuters Brasil, 2020.

diagnostics, can the same understanding be adopted?

For the use of AI software to support medical diagnostic analysis decisions, the potentially liable party may be one or more of the following: (i) the attending physician who recommended and supervised the AI system; (ii) the technician who administered or interpreted the AI system; (iii) the manufacturer who developed and marketed the AI system; and/or (iv) the healthcare institution where the patient was treated.

In addition to the challenge of identifying the person who caused the damage, the trial would require an analysis of the machine's behavior. This is because, in the context of the use of AI to support diagnosis, the doctor can accept or reject the software's response, but the discussion cannot be limited to medical conduct, as it would be a disproportionate judgment of guilt to demand that the doctor always have sufficient parameters to "question" the machine.

According to Miguel Kfouri[20], the doctor cannot be required to have "exceptional knowledge, but rather the means consistent with the criterion of normality", since diagnosis is a process, that is, a "set of medical acts with the purpose of recognizing, identifying and interpreting characteristic signs of the disease, in order to establish the appropriate and necessary therapy to obtain a cure".

Considering that, as seen above, there are still no Brazilian legislative proposals on a specific AI liability regime for the healthcare area, the current legislation - the Civil Code and the Consumer Defense Code - will continue to apply, this author's opinion is that the same reasoning of subjective liability for gross error can be applied when the doctor uses AI systems to support the diagnosis.

In this scenario, the doctor has a duty to make use of all the resources necessary to reach a diagnosis, which would include, if available, decision advice from software such as Watson for Oncology or Harpia Health Solutions. Because of the opacity, the doctor may fail to consider the machine's diagnostic response because he can't understand the correlations made to arrive at the result or can't define which complementary tests could confirm or rule out the machine's hypothesis.

In the hypothetical case, if the software suggestion discarded by the doctor later turns out to be true, could the doctor be guilty of negligence? Since the diagnostic software was an available resource and pointed to a correct answer, albeit with an uninterpretable answer path?

This is a gap that would require consideration of other criteria that have been systematically suggested by Rafaela Nogaroli. The author argues that even with technological advances and the introduction of new products and

[20] Kfouri Neto, Miguel. *Responsabilidade Civil dos Hospitais*. 4th ed. São Paulo: Revista dos Tribunais, 2019.

devices in medicine, which can increase the risk of adverse events, the doctor's subjective liability should be investigated in the event of a breach of the duty of conduct, based on objective good faith and the duty of vigilance.

Although there is a debate about changing the doctor's liability regime from subjective to objective, claiming that medical activity is intrinsically risky, this justification does not hold up. This is because the risk associated with medical treatment is not inherent in the medical practice itself but is often the result of external factors such as the very nature of the patient's illness or risks associated with products supplied by third parties, such as manufacturers. Therefore, changing the doctor's liability regime to an objective model based on the argument of risk inherent in medical activity would be inadequate and inaccurate.

In the discussion on the strict liability of healthcare establishments and developers in the face of unpredictable machine behavior, Cintia Rosa Pereira de Lima's thesis deserves attention. She argues that such behavior should be considered an external accident, beyond the control of the creators of the technology. This perspective leads to the crucial question of whether the risk inherent in technological development can be an excludable cause of liability under the Consumer Protection Code (CDC).

This analysis must balance the interests of patients with those of healthcare establishments and developers. It cannot be assumed, simplistically, that every error made by diagnostic machines is classified as emergent behavior and therefore an exclusion of liability. After all, not all damage results from such behaviour; some may be due to flaws in the development process, characterizing a product defect.

The main challenge is to find a solution that doesn't burden suppliers and developers with excessive responsibilities, discouraging innovation, while also protecting the patient by guaranteeing adequate redress. In this context, the implementation of compulsory insurance emerges as a potential solution, although it could raise the costs of health services.

CONCLUSION

Although the classic theories of civil liability applied to the medical field represent a coherent set of rules for the activity, dividing the debate between the characters patient, doctor, hospital and manufacturer, when we add a fifth character - artificial intelligence - the contours of this division of responsibility can change.

It can therefore be concluded that artificial intelligence in healthcare represents not only a technological revolution, but also a legal and ethical one. The examples of IBM's "Watson for Oncology", the Laura Robot and Onkos Molecular Diagnostics illustrate how AI can significantly improve

diagnostic accuracy and treatment efficiency, contributing to more efficient and personalized medicine. However, the integration of AI into the medical context brings with it important legal challenges, especially with regard to civil liability in the event of errors or damage resulting from its use.

In Brazil's regulatory landscape, Bill 2338 of 2023 represents an important step in the attempt to establish a regulatory framework for AI. However, despite the progress made, the bill still faces criticism and concerns. One of the main challenges is the need for constant updating to keep up with the rapid pace of technological innovation. Issues such as the opacity of algorithmic decisions and the impact of generative AI models, exemplified by ChatGPT, Llama, Bard, among others, are still not sufficiently addressed.

In the European Union, the approval of the Artificial Intelligence Regulation (EU AI Act) in June 2023 marks a significant step, establishing a robust regulatory framework for AI, which includes restrictions on potentially controversial applications and the classification of high-risk AI systems, such as medical devices and generative AI. This regulation reflects a conscious effort to shape the development and use of AI in a way that is safe, ethical and respectful of society's fundamental values.

In conclusion, the contributions of researchers such as Cintia Rosa Pereira de Lima and Mafalda Miranda Barbosa highlight the complexity and urgency of adapting not only the regulatory landscape, but also the civil liability regime to the context of intelligence. Cintia Rosa's work, focusing on civil liability for autonomous cars, and Mafalda Miranda Barbosa's insights into the European scenario, both highlight the unique challenges posed by AI, such as the emerging behavior of machines and the difficulties in establishing culpability and causation in situations where AI is involved.

The emerging behavior of AI, in particular, challenges conventional notions of conduct and causality, complicating the attribution of responsibility and the realization of justice.

The idea of considering the unpredictable behavior of machines as an external fluke, as Cintia Rosa Pereira de Lima suggests, brings up the complexity of assigning responsibility in cases where the emergent behavior of AI is a factor. This raises the question of the extent to which developers and suppliers can be held responsible for algorithm failures.

The purpose of this text is not to present a definitive solution to the complexities addressed, but rather to offer the reader a comprehensive overview of regulation and civil liability in the context of the use of artificial intelligence in healthcare. In this way, it aims to enrich the ongoing debate, contributing fundamental perspectives and reflections to the understanding and evolution of this issue.

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