

Liability of the Spanish Health Administration for the Use of Artificial Intelligence*

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ABSTRACT The development of disruptive technologies such as artificial intelligence undoubtedly facilitates various human activities, but requires enormous efforts from legislative institutions to regulate these technologies in a way that guarantees the protection of people's rights without hindering innovation. This paper, by analyzing each of the requirements identified by the Spanish judicial bodies for the determination of liability against the Public Administrations, demonstrates precisely the need to update this regime, specifically in the field of public health, since it is not designed to be applied to damages caused by artificial intelligence. In addition, this analysis contributes to the identification of certain key aspects that must be considered when designing a specific regulation under European Union directives and guidelines.

1. Introduction

The history of mankind has been characterized by constant technological development, facilitating the execution of all types of activities, and improving living conditions. During the last three centuries, it is possible to identify four industrial revolutions that have defined progress for mankind.

The First Industrial Revolution, tied to the invention of the steam engine and the development of railroads, considerably facilitated mass transportation of materials and people. The Second Industrial Revolution was defined by electricity and the implementation of the assembly line in mass production. The Third Industrial Revolution yielded the widespread use of electronics, the invention of computers and the use of digital-information technology to automate production and facilitate communication on a global scale. And finally, the Fourth Industrial Revolution is ongoing and is characterized by the implementation of nanotechnology, robotics, biotechnology and, above all, artificial intelligence, which has allowed for an exponential increase in the capacity to store and process information, with smaller margins

of error than the ones achieved by the cognitive capacities of humans.¹

The enormous advantages generated by technological development are unquestionable. For example, artificial intelligence has created machines capable not only of processing a greater amount of data and at greater speed than human beings, but also of executing actions with greater precision and effectiveness.

Without undermining these obvious advantages, these types of technologies have recently confronted mankind with enormous challenges. People are now exposed to new, previously unsuspected risks with very significant ramifications in the legal sphere.² It is no coincidence that the adoption of each technological invention, and the transition to a new industrial revolution, has been followed by the enactment of appropriate regulatory frameworks. Such are the examples for frameworks regarding terrestrial and aerial transportation, electric power, oil exploitation, cybersecurity, privacy, etc. These efforts have marked the history of mankind, evidencing the perpetual pursuit between law and human development. This pursuit has even accelerated with the Third and Fourth Industrial Revolutions, where humanity has been exposed to the so-called risks of digital freedom, creating situations where a large

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¹ J.G. Corvalán, *Inteligencia Artificial: retos, desafíos y oportunidades – Prometea: la primera inteligencia artificial de Latinoamérica al servicio de la justicia*, in *Revista de Investigaciones Constitucionales*, vol. 5, no. 1, 2018, 296-297.

² K. Schwab, *La Cuarta Revolución Industrial*, Barcelona, Debate, 2016, 20-21.

percentage of the world's population has unconsciously given up a significant part of their freedom and privacy.

On the other hand, the advantage of global communication and access to almost-instantaneous information, as well as the existence of artificial-intelligence systems that feed on this information, has limited the capacity of nation-states to exercise democratic control. In this context, the need of political institutions that can establish an effective regulatory framework globally is imminent.³ These institutions must be characterized by a preventive, rather than reactive, nature, thus, distancing themselves from rigid and inoperative national or supranational legal systems currently in existence.

It is precisely here, that the imminent need to study the legal implications of the development and use of artificial intelligence systems lies. The need to tackle this issue becomes an existential imperative in areas where fundamental rights of individuals may be seriously violated, such as health, taking into consideration that: "Successful modernization and rapid technological evolution have catapulted us into areas where we can and must act, without providing us with the vocabulary we need to adequately describe or name those areas and our options for action. (...) We tend to say that a new digital empire is being born. But none of the historical empires we know - neither the Greek, nor the Persian, nor the Roman Empire - was characterized by the features that mark the digital empire of today. The digital empire is based on features of modernity that we have not yet really thought about. It does not rely on military violence, nor does it seek to integrate politically and culturally distant areas into its own realm. It does, however, exercise an exhaustive and intensive, deep and far-reaching control that ultimately pushes any individual preferences and deficits into the open terrain: we are all becoming transparent".⁴

It is evident, then, that focus should be directed on these insights and on the sociological and legal analysis of both national and supranational liability regimes.

The goal is to identify their shortcomings in relation to the challenges posed by the use of artificial intelligence and propose feasible and effective reforms. The ultimate objective is the establishment of a functional global regime for the assessment and recognition of legal liability and the fair allocation of risk across all the different sectors of society.

To contribute to this objective, the following analysis will focus on the liability regime of the Health Administration currently in force in Spain. It will consider not only current EU regulation but also the legislative projects that have not yet been enacted. The analysis will begin with the identification of the constitutional provisions and the legal norms that regulate this regime. Subsequently, it will assess the applicability of this regime to the damages caused using artificial intelligence in the provision of health services.

2. *The liability regime of the Health Administration in Spain*

The right to health protection is recognized in Article 43 of the Spanish Constitution, which imposes the duty on public authorities to organize and protect health, adopting preventive measures and guaranteeing the provision of the necessary services to individuals. Accordingly, Article 41 orders public authorities to maintain a public and universal Social Security system available for all citizens.

In application of these constitutional rights and guarantees, Law 14/1986, enacted on April 25th, 1986, created the National Health System (NHS) and configured healthcare as an improper public service, allowing the adoption of indirect-management formulas and making room for private initiative.⁵ These legal provisions have made the Spanish healthcare administration extremely complex and heterogeneous, as it is made up not only of public institutions, which include regional services, but also of other types of institutions created on the basis of public-private models. Health-care service providers, including public authorities, can thus avail themselves of a wide array of legal forms, including the concession of the management of the services to private entities.

³ U. Beck, *El riesgo de la libertad digital. Un reconocimiento demasiado frágil*, in *Cuadernos del Mediterráneo*, no. 22, 2015, 313-314.

⁴ *Ibidem*, 313.

⁵ M. Cueto Pérez, *Responsabilidad Patrimonial de la Administración y Gestión Privada de Servicios Sanitarios - Incidencia de las Leyes 39/2015 y 40/2015 en el Modelo Actual*, in *Derecho y Salud*, vol. 26, 2016, 334.

The heterogeneous nature of the entities and organizations that provide healthcare services in Spain has caused problems regarding the definition of the liability regime applicable to their actions or omissions. However, the enactment of the twelfth additional provision of the now repealed Law 30/1992, which stated the Legal Regime of the Public Administrations and Common Administrative Procedure (LRJPAC), allowed a peaceful application of the liability regime provided on article 106.2 of the Spanish Constitution and in article 139.1 of Law 40/2015.

The liability regime for institutions that are part of the NHS is currently opaque, particularly considering the suppression of the Additional Provision enacted by Laws 39/2015 and 40/2015. This is further complicated by case law that subjects private-law entities that provide health services, to the private—instead of public—liability regime provided in Articles 1902 and 1903 of the Civil Code.⁶

However, since this paper focuses on the liability for the use of artificial intelligence by the Public Health Administration in Spain, undoubtedly the applicable legal regime is the one provided in Article 32.1 and 32.2 of Law 40/2015, that regulates the Legal Regime of the Public Sector (LRJSP): “1. Individuals shall have the right to be compensated by the corresponding Public Administrations for any injury they suffer to any of their property and rights, when the injury is a consequence of the normal or abnormal operation of public services, except in cases of force majeure or damages where the individuals, or private entities, have the legal duty to bear in accordance with the Law. (...) 2. In any case, the alleged damage must be effective, economically assessable and individualized in relation to a person or group of persons”.

This general provision has not been further regulated for specific cases or purposes. Spanish legislation lacks specialized regulations and infra-legal dispositions to adapt the regime to specific activities or sectors of the Public Administrations. This lack of regulation has given an enormous discretion to judicial bodies in the application of this regime, particularly, when defining its

main characteristics. In this regard, case law lack homogeneity. Contradictory rulings are widespread, especially regarding legal requirements for liability, such as the need for fault in the conduct of the Public Administrations and the legal duty of the private parties to bear the damage in accordance with the Law.

Nonetheless, the majority of the Spanish jurisprudence agrees that the liability of the Public Administration recognized in the aforementioned article is: a) unitary, as it applies to all the Public Administrations provided for in Article 149.1.18 of the Spanish Constitution; b) general, as it refers to all the activities and inactivities of the Administration, whether legal or factual; c) direct, as it falls on the Administration and not on the public official acting on its behalf, and, finally; d) strict or objective, as fault is not supposed to be a relevant factor in determining liability. Nevertheless, courts normally require some degree of fault in the underlying administrative action upon which the claim is based, to recognize the right of individuals, or private entities, to be compensated.⁷

As mentioned before, since the inception of this liability regime in the 1950s, its application has presented enormous challenges to judicial entities. These challenges will undoubtedly increase with the implementation of new technologies for the provision of public-health services. This is due to the fact that the use of systems or machines with artificial intelligence in the provision of health and/or paramedical services casts doubt on the usefulness of the classic requirements that are essential for the recognition of liability against Public Administrations.

These requirements will be analyzed from the perspective of the possible damages that the use of artificial intelligence may cause to individuals. In addition to this, we will identify certain legislative reforms that should be implemented to adapt to the new landscape derived from the invention of new autonomous and artificially-intelligent tools.

⁶ M. Cueto Pérez, *Responsabilidad Patrimonial de la Administración y Gestión Privada de Servicios Sanitarios*, 360-361.

⁷ L. Martín Rebollo, *La Responsabilidad Patrimonial de las Administraciones Públicas*, in *Manual de las Leyes Administrativas*, 3th Ed, Cizur Menor, Aranzadi Thomson Reuters, 2019, 11.

3. The liability of the Spanish public health administration for damages caused using artificial intelligence

The judicial application and interpretation of Article 32, which regulates the right recognized in article 106.2 of the Spanish Constitution,⁸ has identified three main requirements for the Public Administration to be held liable for the actions or omissions of its officials. The first, consists of the existence of a compensable injury, understood as actual, real, economically assessable, individualized damage to a person or a group of persons, and unlawful, i.e., that the affected party does not have the legal duty to bear. The second, comprises the existence of an action or omission of the Health Administration, in charge of the operation of public services. And finally, the third requirement involves a direct and immediate causal relationship between the action or omission and the injury suffered by the individual.⁹

In this sense, the claimant seeking compensation from the Public Administration for injuries caused by its services must, in principle, prove each of the elements set out above. Under the general-liability regime this burden of proof already represents a real obstacle for victims. In regards to liability caused by the use of artificial intelligence, this burden will increase significantly, since this type of technology is characterized by: the opacity of its decision-making processes,¹⁰ its technical complexity, its enormous openness to new information and its frequent necessity of information inputs once they have been put into circulation.¹¹

This first challenge highlights the need for reforms to the regime of Public Administration's liability, by means of specific regulations, aimed at the prevention of this type of obstacles. This is especially necessary in the healthcare field. Undoubtedly, this difficulty should not cause the Health Administration to be irresponsible

when it uses artificial-intelligence systems in the provision of its services, so the legislator can opt for some alternatives that have already been identified by specialists, such as the inversion of the burden of proof for certain elements or the presumption of causality in disproportionate damages.¹²

The risks associated with legislative inaction are significant. The maintenance of the current deficient regulatory framework could have dire consequences, such as skepticism between patients who could benefit from treatments or surgeries where artificial-intelligence tools or machines are used. Thus, an inadequate legal framework may result in depriving NHS patients of the countless benefits that these technological advances offer.

3.1 Existence of a compensable injury using artificial intelligence

3.1.1. Damages that can be caused using artificial intelligence

Today's artificial-intelligence systems, by feeding on a large amount of data, can contribute to aspects such as the design of public-health policies, the diagnosis and treatment of diseases and the monitoring of the spread of contagious diseases.

However, the risks involved in the use of this type of technology in public institutions, hospitals and other entities that make up the NHS are also evident. For example, the information used by this type of system will generally consist of personal data, medical records and intimate or confidential patient information. Therefore, its creators or programmers must not only be subject to strict ethical principles, but also comply with legal requirements that guarantee the rights of individuals¹³ and the protection of that information.

Despite the adoption of these measures, the malfunction or illegal use of systems with artificial intelligence can undoubtedly generate compensable injuries to individuals. The legal duty to bear such injuries could not be imposed, since these would unlawfully violate express provisions of the Organic Law

⁸ Spanish Supreme Court Ruling of 22 December 1997.

⁹ J. A. Hurtado Martínez, *Responsabilidad Objetiva Patrimonial de la Administración Sanitaria: Doctrina Legal del Consejo de Estado y del Tribunal Supremo*, in *Boletín de la Facultad de Derecho de la UNED*, no. 18, 2001, 304.

¹⁰ D. Parra Sepúlveda and R. Concha Machuca, *Inteligencia artificial y derecho. Problemas, retos y oportunidades*, in *Universitas*, vol. 70, 2021, 6.

¹¹ European Commission, *Report of the Expert Group on Liability and New Technologies*, 2019, 33.

¹² *Ibidem*, 48.

¹³ A. Platero Alcón, *Breves Notas sobre el régimen de responsabilidad civil derivado de los sistemas de inteligencia artificial: especial referencia al algoritmo de recomendaciones de Netflix*, in *Ius Et Scientia*, vol. 21, no. 1, 2021, 136.

3/2018 on Personal Data Protection and Guarantee of Digital Rights as well as other legal rules that prevent the disclosure of this type of information.

It has also been shown that the use of artificial-intelligence tools can, on certain occasions, give results or diagnoses biased by human prejudices, like race and gender.¹⁴ In the health field, biased results can cause extremely serious injuries to individuals and even violations of human rights and fundamental principles such as equality and non-discrimination of especially-vulnerable sectors of the population.

Finally, there are also more obvious risks associated to the use of systems or machines with artificial intelligence by the Health Administration. These risks consist of injuries to protected legal assets such as health, physical integrity and even the life of individuals. In this regard, it is worth taking into account the possibility that artificial-intelligence systems may misdiagnose patients or, less frequently, where the malfunctioning of autonomous or semi-autonomous surgical robots, such as CyberKnife and AESOP, may have enormous repercussions on the health of patients.¹⁵

Therefore, it is necessary to properly update these legal systems to new technologies with the purpose of avoiding the proliferation of claims and lawsuits by patients. Taking also into account that the greatest challenges will continue to arise, especially when determining whether the damage can be considered unlawful or, on the contrary, whether the individual has the legal duty to bear it. This characteristic, which turns the damage into a compensable injury, has brought enormous difficulties to Spanish jurisprudence, to the point of demanding fault of the administrative action or omission despite the applicable legal regime is supposedly objective or strict.¹⁶

In the healthcare field, the case law of the Supreme Court has seen the need to exclude

from the supposedly strict-liability regime, the so-called medical acts themselves, where the application of liability criteria based on negligence for breach of the *lex artis* is inherent.¹⁷ In this sense, since the nineties, the specialized doctrine has pointed out: “Within this progressively profiled panorama that the matter presents today, one can detect, on the one hand, as in so many other areas, a tendency towards the objectification (becoming strict) of liability. An objectification that seeks to offer reparation to the victims of the damages that are frequently inflicted on users in these complex care establishments that attend to them, responding to criteria of social solidarity rather than of strict culpability. However, alongside this perceptible tendency, the idea that the personal liability of the physician or any other healthcare professional can only be based on guilt, that is, on the personal reproach ability of his or her conduct, remains firm. This idea is firmly anchored in the case law of the Supreme Court and means, in the end, that the aforementioned objective (strict) nature of health liability extends to the public health service authorities, or even to private healthcare centers, but not to the medical professional as such”.¹⁸

This differentiation between public health services and medical acts must be considered when analyzing the liability of the Health Administration for the use of systems with artificial intelligence, especially because this type of technology can cause damage in both areas of public service. On one hand, programs (*software*) with artificial intelligence used to facilitate the provision of public-health services are obviously capable of causing damage to their users. On the other hand, it is also possible that medical acts, performed by surgical robots, cause damage to patients.

In addition, the Health Administration can also be held liable for damages caused by defective artificial-intelligence systems, since

¹⁴ G. Lain Moyano, *Responsabilidad en inteligencia artificial: Señoría, mi cliente robot se declara inocente*, in *Ars Iuris Salamanticensis*, vol. 9, 2021, 199.

¹⁵ T.G. García Micó, *Litigación asociada a la cirugía robótica en el Da Vinci*, in *InDret – Revista para el análisis del Derecho*, no. 4, 2014, 10-11.

¹⁶ O. Mir Puipelat, *Responsabilidad objetiva vs funcionamiento anormal en la responsabilidad patrimonial de la Administración sanitaria (y no sanitaria)*, in *Revista Española de Derecho Administrativo*, no. 140, 2008, 646.

¹⁷ Spanish Supreme Court Ruling No. 1806/2020 of 21 December 2020; Spanish Supreme Court Ruling No. 50/2021 of 21 January 2021; Spanish Supreme Court Ruling No. 92/2021 of 28 January 2021; Spanish Supreme Court Ruling No. 824/2021 of 9 June 2021; Spanish Supreme Court Ruling No. 1340/2021 of 17 November 2021; Spanish Supreme Court Ruling No. 1423/2021 of 1 December 2021; and Spanish Supreme Court Ruling No. 272/2022 of 3 March 2022.

¹⁸ J. Pemán Gavín, *La responsabilidad patrimonial de la Administración en el ámbito sanitario público*, in *Documentación Administrativa*, no. 237-238, 1994, 285.

their acquisition is related to the organizational part of the health services and not to medical acts themselves.¹⁹ In these cases, strict liability should be applied more rigorously.

3.1.2. Criteria for determining the unlawfulness of damages caused using artificial intelligence

In order to avoid the existence of contradiction in judicial decisions regarding the unlawfulness of the damage, criteria have been developed, first in jurisprudence and later in law, to determine whether or not the individual has the legal duty to bear the damage.

As mentioned above, one of these criteria constantly applied by Spanish jurisprudence, especially in the healthcare field, is that prescribed in Article 34.1 LRJSP: “Article 34. Indemnification. Compensation shall only be payable for injury to the individual arising from damage which he has no legal duty to bear in accordance with the law. Damage arising from facts or circumstances which could not have been foreseen or avoided according to the state of knowledge of science or technology existing at the time of their occurrence shall not be compensable, without prejudice to the assistance or economic benefits which the laws may establish for these cases”.

The application of this criterion, commonly known as *lex artis*, was of vital importance in resolving cases regarding the liability of the Health Administration for contagion with the HIV or Hepatitis C virus to patients who underwent blood transfusions. In AIDS-related cases, the Supreme Court determined that until 1985, the state of the art did not enable the detection of the HIV virus in blood. Therefore, all transfusions performed prior to that year did not give rise to liability on the part of the Health Administration because the injury was not unlawful.²⁰ In other words, when the state of scientific knowledge prevents the Health Administration from knowing the potential risk of causing the

damage, individuals have the legal duty to bear it.

The proven usefulness of this guiding criterion, which is closely related to the due diligence of doctors or nurses when providing healthcare services, led to its inclusion in the cited legal disposition. However, its application by the case law of the Supreme Court has not been limited to medical acts *per se*, but has also been extended to the provision of healthcare services in general, which undoubtedly seems excessive and contradictory to other rulings of the same judicial entity.²¹

The vagueness in the application of this criterion by judicial institutions means that its application to damages produced by AI machines or programs may be detrimental to the users of the healthcare system, considering that the knowledge of the risks and consequences of AI is still extremely limited.²² This type of technology is still unpredictable, especially because it can learn autonomously by constantly feeding itself with new information and because the risks to humans are still unknown to the science. Therefore, as the autonomy of robots and AI machines increases, the irresponsibility of the Health Administration in these cases will clearly become the general rule in application of article 34.

On the other hand, unlike the criterion analyzed above, the existence of prior and informed consent on the part of the victim can be useful when determining the unlawfulness of the damage, especially in cases of Health-Administration liability for the use of AI. In such cases, the patient’s lack of knowledge of the risks should be considered at the time of undergoing an intervention or treatment. It is precisely this type of area of administrative activity that represents a greater risk for individuals, so it is essential that they are guaranteed the possibility of deciding for themselves within the scope of their individual sphere and autonomy of will.²³

In this regard, Spanish jurisprudence has

¹⁹ M. Cueto Pérez, *Jurisprudencia en el caso Ala Octa: Responsabilidad Patrimonial por la utilización de Productos Defectuosos en el Ambito Sanitario*, in *Revista de Administración Pública*, no. 217, 2022, 178-183.

²⁰ M. Ortiz Fernández, *La Responsabilidad Civil Derivada de los Daños Causados por Sistemas Inteligentes y su Aseguramiento - Análisis del Tratamiento ofrecido por la Unión*, Madrid, Dykinson SL, 2022, 116.

²¹ M. Cueto Pérez, *op. cit.*, 186-187.

²² C. Gómez Liguere and T. García-Micó, *Responsabilidad por uso de Inteligencia Artificial y otras tecnologías emergentes*, in *InDret - Revista para el Análisis del Derecho*, no. 1, 2020, 509.

²³ A. L. Rivas López, *Responsabilidad Patrimonial de la Administración Sanitaria (aspectos de su práctica administrativa y procesal)*, Málaga, Fundación Asesores Locales, 2012, 117.

stated: “The specific content of the information transmitted to the patient to obtain his consent may condition the choice or rejection of a given therapy because of its risks (...) the prior information may also include the benefits to be derived by the patient from doing what is indicated and the risks to be expected otherwise (...)”²⁴

Due to the above, in addition to what is prescribed in article 2.2. of Law 41/2002, which regulates Basic Patient Autonomy, the Health Administration should be legally required to inform patients or users of both the risks and benefits involved in the use of artificial intelligence, as well as the risks and benefits involved in not subjecting them to surgical interventions or treatments where this type of technology is used. Thus, in the event of a claim, the damage would not be considered unlawful if there was prior consent by the patient to subject him/herself to the risky use of AI. On the contrary, if the Health Administration cannot prove the existence of such consent, the judge should consider that the individual does not have the legal duty to bear the compensable injury.

In other words, the application of the *lex artis* can exonerate responsibility on the part of the Health Administration, in cases where there is little knowledge of the risks, as in the case of the use of AI, but it can be useful when one of its manifestations, such as the patient’s prior and informed consent, is correctly applied.

However, additional legal or jurisprudential criteria should be identified²⁵ to provide objectivity and predictability to the liability regime of Public-Health Institutions, for the benefit of patients analyzing the feasibility of filing a claim. Considering, moreover, that the unlawfulness of the injury is an element commonly used by case law to reject the liability of the Public Administration,²⁶ precisely because of its

abstract and vague nature.

3.2. Action or omission of the Public Administration

The liability of the Health Administration for the use of AI can arise from the material conduct of its public servants, whether they are doctors, nurses, assistants or even providers of paramedical services such as cleaning, maintenance and, obviously, IT. However, the use of AI is not limited to this type of activity of the Health Administration as it can also be employed in the technical motivation of formal acts, of regulatory and/or administrative nature.

Furthermore, it cannot be ruled out that, soon, autonomous AI systems will be used to issue formal acts for the Public Administration, and their annulment may be subject to liability. In this sense, their annulment may occur under various circumstances such as a technically erroneous motivation or fundamental-rights violation.

Nevertheless, as the administrative formal acts are indisputably attributable to the Public Administration, there are greater challenges in cases of the participation of the systems with IA in material actions. Considering that the IA can replace, totally or partially, the conducts of the public servants, it becomes necessary to analyze what the doctrine calls the first-level imputation in this type of cases.

3.2.1 First-level imputation - attribution of the conduct to the Health-Care Administration

According to doctrine, the application of the first-level imputation requirement entails an analysis of those instances in which a conduct, carried out by a natural person, can be attributed to the Public Administration. Therefore, it can be stated that there has been a functioning of public services.²⁷ In this sense, all the actions or omissions of natural persons, who are integrated in the administrative organization and who act in the exercise of their legal roles will be imputable to the Administration.²⁸

Likewise, due to the fact that health

ria: El criterio de la Lex, in *La Responsabilidad Patrimonial de la Administración Sanitaria*, Madrid, Consejo General del Poder Judicial, 2002, 82 - 83.

²⁷ O. Mir Puigpelat, *La Responsabilidad Patrimonial de la Administración Sanitaria - Organización, Imputación y Causalidad*, Madrid, Civitas Ediciones, 2000, 43.

²⁸ O. Mir Puigpelat, *op cit.*, 144.

²⁴ Spanish Supreme Court Ruling of 4 April 2000 - RC 8065/1995.

²⁵ There are authors who recognize as a guiding criterion on the clinical situation of the patient, which is also applicable to cases of the use of artificial intelligence. Clearly, cases in which the patient is admitted with a critical situation cannot be treated as those in which the patient is admitted in a stable situation (J. E. Rebés Solé, *La Responsabilidad Patrimonial por asistencia sanitaria desde la perspectiva de los órganos consultivos*, in *Revista Española de la Función Consultiva*, no. 1, 2004, 90).

²⁶ J. Guerrero Zaplana, *Las peculiaridades de la Responsabilidad Patrimonial de la Administración Sanita-*

activity is legally configured as a public service, the Health Administration is also liable for: a) injuries caused by the conduct of natural persons belonging to private-law entities, which were created by the Health Administration for the provision of health care; and b) injuries caused by private contractors, in compliance with an order or obligation expressly imposed by the contracting entity itself.²⁹ All this is based on the provisions of article 121.2 of the Law of Forced Expropriation³⁰ and article 32.9 LRJSP.

However, the use of AI systems by the Public Administration in general, and by the Health Administration in particular, may result in the recognition of liability for those conducts carried out by subjects specifically identified for this technology.

In this sense, AI specialists initially considered that the liability for damages caused by AI systems or products lies on the manufacturer, the designer, the hardware developer, the operator, the owner or the user, depending on the subject that could have anticipated, foreseen and prevented its malfunction or illegal use. Albeit, currently, it seems more convenient to simplify these subjects into two categories: the first one called *Back End* operators includes the person who operates the system, but does not use it (updates the software, introduces improvements, reviews and monitors); and the second one called *Front End* operators, which are the individuals who operate the system and use it or benefit from it (examples: owner, user or holder).³¹

Although such subjects have been identified for the scope of civil liability, which is characterized by being based on fault, they can also be applied to the Public Administration's liability regime. Thus, demonstrating the importance of the recently enacted Artificial Intelligence Act,³² since there was no special regulation either at European level, or in Spain.³³

²⁹ *Ibidem*, 128.

³⁰ In the provision of public services, the compensation shall be borne by the concessionaire, except in the event that the damage has its origin in some clause imposed by the Administration on the concessionaire and which is unavoidable for the latter to comply with.

³¹ G. Lain Moyano, *op cit.*, 206.

³² COM (2021) 206 - Brussels, 21 April 2021.

³³ On this regard review: M, Ortız Fernandez, *La Responsabilidad Civil Derivada de los Danos Causados por Sistemas Inteligentes y su Aseguramiento - Analisis*

The enactment of this Act will surely nurture the Public-Administration liability regime with these types of concepts and facilitate the regulation of this legal regime, since it seems reasonable to consider that the conduct of individuals included in *Front End* and *Back End* categories can lead to the Health Administration being obliged to compensate individuals for damages caused using AI. This considering, firstly, that the Administration is included in the *Front End* category when it is the owner, user or possessor of this type of technology. In less frequent cases, it could also be included in the *Back End category*, when the subjects responsible for updating the software, introducing improvements, reviewing and supervising this type of systems, are contractors or public servants belonging to the Health Administration. This implies that the Health Administration should be liable for the conduct of *Back End* operators when the conditions prescribed in the legal provisions of the LEF and the LRJSP are met.

However, the actual lack of specific regulations on liability for the use of AI, forces the application of the consumer-defense legislation contained, at the European level, in Directive 85/374/EEC of July 25, 1985 and, in Spain, in the General Law for the Defense of Consumers and Users.³⁴ This focuses solely on the liability of the producer or manufacturer and, therefore, excludes from its scope of application the other agents involved in the operation of an AI product,³⁵ which will make it difficult to apply liability to the Health Administration.

In this regard, Spanish case law has pointed out that: “*the objective (strict) nature of the liability provided in the aforementioned legislation on consumers and users does not include, extend to or cover the so-called “medical acts themselves” “*, such as surgical interventions. Consequently, the Supreme Court has rejected the liability of the Health Administration when this is caused using defective products in surgical interventions, especially when such defects have been alerted after their application.³⁶

del Tratamiento ofrecido por la Union Europea, Madrid, Dykinson SL, 2022, 72 -81.

³⁴ Real Decreto Legislativo No. 1/2007 of 16 November 2007. Boletın Oficial del Estado No. 287, of 30 November 2007.

³⁵ M. Ortız Fernandez, *op. cit.*, 64-68.

³⁶ Spanish Supreme Court Ruling No. 1806/2020 of 21

Based on these considerations, case law has been inclined to conclude that liability falls on the producer or manufacturer and on the public institution responsible for guaranteeing and controlling quality. Limiting the application of a strict liability regime to the Public Administrations obliged to control the use of artificial-intelligence systems and excluding its application to the Health Administrations that provide services using this type of technology.

On the other hand, it is highly unlikely that public institutions intervene as manufacturers or producers of AI systems to justify an application of this regime to institutions of the NHS. Likewise, the application of this regime to cases in which the manufacturer or producer is a public contractor is obviously complicated.³⁷ Especially, due to the challenge of qualifying certain AI systems as defective products, given that they are not in the nature of tangible goods.³⁸

Therefore, it is vital to enact specific legislation regulating liability for the use of AI and to create an administrative institution to control its quality, otherwise it would be difficult for victims to hold the Public Administration responsible or co-responsible for injuries caused by this type of technology.

3.2.2. Liability-imputation titles

In accordance with the provisions of article 32 LRJSP, the basic criteria in the liability regime of the Health Administration lies in the administrative ownership of the activity or service in which the damage has occurred. Thus, when the victim proves that the injury was caused in the performance of an activity whose ownership corresponds to an Administration, the latter will be obliged to compensate.³⁹

In other words, the healthcare administration can now be held responsible even for the conduct of its non-healthcare

personnel (statutory),⁴⁰ which includes the computer technicians responsible for the proper functioning of the systems that use AI.

However, as technological development grants greater autonomy to this type of systems, their use by the Health Administration will bring additional difficulties regarding liability. Although there is still no such thing as strong AI, understood as an AI that can perform the same intellectual tasks as a human being,⁴¹ its use in the future cannot be imputed to the Health Administration, since the current regime is designed to be applied to human conducts.

On this point, it is important to analyze the advisability of future legislative reforms so that autonomous robots using strong artificial intelligence are recognized as electronic persons, and therefore, the possibility of holding the Health Administration liable for the actions or omissions of electronic public servants. In this regard, I find convincing the experts' position that the legal recognition of electronic persons generates more problems than solutions, mainly because it exempts their manufacturers, operators, or programmers from liability.⁴²

For the time being, it seems sufficient that the provisions of article 121.2 LEF and 32.9 LRJSP are not limited to the concessionaire but apply also to contractors and other parties involved in the operation of an IA system or machine. Thus, it should be specified that the liability of the Health Administration needs to be recognized in cases where it is not clear whether the damage is attributable to the *Back End* operators of the IA system, or to their *Front End* operators (where the Health Administration is included). In the same sense, the liability should be expressly recognized in cases where the damage is caused by a contractual clause imposed by the Administration unavoidable for the contractor.

The above is related to another liability criterion foreseen by the European Artificial Intelligence Act, which could be adjusted to the Health-Administration liability regime. This liability criterion consists of the risk generated by the AI and determines that the person who can control this risk and benefits from its operation, should be the one held

December 2020; Spanish Supreme Court Ruling No. 50/2021 of 21 January 2021; Spanish Supreme Court Ruling No. 92/2021 of 28 January 2021; Spanish Supreme Court Ruling No. 824/2021 of 9 June 2021; Spanish Supreme Court Ruling No. 1340/2021 of 17 November 2021; Spanish Supreme Court Ruling No. 1423/2021 of 1 December 2021; and Spanish Supreme Court Ruling No. 272/2022 of 3 March 2022.

³⁷ G. Laín Moyano, *op. cit.*, 212.

³⁸ Consider article 136 of the Spanish General Law for the Defense of Consumers and Users.

³⁹ O. Mir Puigpelat, *op. cit.*, 54.

⁴⁰ *Ibidem*, 171-172.

⁴¹ G. Laín Moyano, *op. cit.*, 201.

⁴² C. Gómez Liguerra and T. García-Micó, *op. cit.*, 506-509.

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liable.⁴³ In other words, the liability falls on the *Front End* operator which, in this case, is the Health Administration, mainly because this is the only one that controls the conditions under which the health service is provided and, consequently, is able to control the risk to which patients are subject at the time of using such technology.

Using this criterion, the aforementioned Act gives a differentiated treatment to the following categories of sectors, uses or purposes of artificial intelligence: on the one hand, there are the high-risk ones and determined by inclusion in an exhaustive and cumulative list, and, on the other hand, the low-risk ones, determined by logical exclusion with respect to the previous ones.⁴⁴ The provision of public services entrusted to the Healthcare Administration unquestionably falls into the first category, together with, for example, self-driving cars and AI systems in financial and stock-market matters that allow users to decide where to invest in the stock market, etc. Such uses or sectors obviously generate greater risks than those that could be caused by a smart speaker.⁴⁵

The interesting aspect about this differentiation with respect to the liability of the Public Administration is that the sectors that represent a high risk would be subject to a regime of strict liability, and, on the contrary, those of low risk would be subject to a regime of subjective liability or negligence-based liability.⁴⁶ Therefore, the liability regime of the Health Administration currently applied in Spain coincides with the liability regime that the European Union impose specifically on the use of AI in the health sector.

Even in the *Liability Report for Artificial Intelligence and other emerging digital technologies*, the group of high-level experts expressly point out that the recognition of strict liability is an appropriate response to the risk generated by the use of emerging digital technologies, especially when these technologies are being used by public entities and significant damage can be caused to individuals.⁴⁷

⁴³ *Ibidem*, 508.

⁴⁴ A. Tapia Hermida, *La responsabilidad civil derivada del uso de la inteligencia artificial y su aseguramiento*, in *Revista Ibero-Latinoamericana de Seguros*, vol. 30, no. 54, 2021, 118.

⁴⁵ A. Platero Alcón, *op. cit.*, 137.

⁴⁶ *Ibidem*, 139-141.

⁴⁷ European Commission, *Report of the Expert Group*

The liability of the Health Administration for the use of AI should be based on the risk that this use entails for the patients of the Spanish National Health System.

However, regarding risk as a liability criterion, it is necessary to take into account the case law of the Supreme Court that has rejected the liability of the Health Administration for the use of defective products, considering that in these cases the risk does not derive from the application of the product or from the medical act, but from its manufacture and the lack of control by the Public Administration.⁴⁸ Such consideration, undoubtedly, will also be applied with the purpose of disregarding the liability of the Health Administration that uses AI in medical acts and in the provision of health services in general.

3.3. Causal relationship between the conduct and the damage – second-level imputation

This third element of the Health Administration's liability is called by some authors as second-level imputation, as it analyzes the relationship that must exist between the damage and the operation of the public service for the Administration to be obliged to pay compensation, as opposed to first-level imputation which, as detailed above, analyzes the relationship between the conduct and a specific subject responsible for its consequences.⁴⁹

Spanish case law initially required a direct, immediate, and exclusive causal relationship to recognize the liability of the Health Administration. Subsequently, the Supreme Court has pointed out that it cannot exclude the possibility that this causal relationship may appear under other more mediate, indirect, or concurrent forms that may or may not cause a moderation in the liability.⁵⁰

However, the recognition of the causal nexus in such a broad sense seems to cause

on Liability and New Technologies, 2019.

⁴⁸ Spanish Supreme Court Ruling No. 1806/2020 of 21 December 2020; Spanish Supreme Court Ruling No. 50/2021 of 21 January 2021; Spanish Supreme Court Ruling No. 92/2021 of 28 January 2021; Spanish Supreme Court Ruling No. 824/2021 of 9 June 2021; Spanish Supreme Court Ruling No. 1340/2021 of 17 November 2021; Spanish Supreme Court Ruling No. 1423/2021 of 1 December 2021; and Spanish Supreme Court Ruling No. 272/2022 of 3 March 2022.

⁴⁹ O. Mir Puigpelat, *op. cit.*, 44.

⁵⁰ A. L. Rivas López, *op. cit.*, 109.

that, in certain circumstances, it is confused with the unlawfulness of the injury. As, for example, in cases where it is considered that the negligent and deliberate conduct of the injured party himself breaks the causality relation, when in fact such action or omission imposes the legal duty to bear the damage, since it is the patient who placed himself/herself in the situation of risk.⁵¹

Based on the above, especially in cases of use of AI by the Health Administration, it seems appropriate to apply the theory of objective imputation, which rejects legal considerations when determining the causal link and argues that causation will always be a naturalistic, empirical notion, completely independent to normative-valuative considerations.⁵² Therefore, the causal relationship between the use of AI by the Health Administration and the compensable injury caused to the individual should always be determined based on technical or scientific considerations.⁵³

It is mainly the regulation of these criteria for assessing the causal relationship that the European Union seeks with the issuance of the Proposal for a Directive of the European Parliament and of the Council on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive),⁵⁴ by stating in the explanatory memorandum that: "In the public's view, the "black box" effect may make it difficult for the victim to prove fault and causation, and may create uncertainty as to how the courts will interpret and apply existing national liability rules in cases involving AI".

Based on these considerations, the Proposal for a Directive regulates non-contractual civil liability, without ruling out that its provisions may be applied to the Public-Administration liability regime. It also provides provisions aimed at easing the burden of proof in a very specific and proportionate manner, through the use of the production of relevant evidence relating to specific high-risk AI systems suspected of having caused damage (Article 3); and rebuttable presumptions (*iuris tantum*) regarding the causal link between the defendant's fault and the results produced by the AI system or the non-production of results by the AI system, when certain special

conditions are met (Article 4).

Finally, in the field of artificial intelligence, there are complications in the circumstances where causality is broken, such as force majeure or other cases where the jurisprudence applies a concept known as concurrence of causes.

Regarding force majeure, case law has indicated that the rupture of the causal link is given by an event that has been irresistible, even in the case that this could be foreseeable and external, in the sense that this is alien to the service and the risk that is proper to it.⁵⁵ Based on these characteristics, a clear example in the field of AI would be the malfunction of a surgical robot during surgery, due to a sudden power failure caused by a traffic accident. Evidently, in this case the damage was caused by causes beyond the control of the Health Administration that have no relation to the risk that the use of AI represents to the patients of the NHS.

The legal concept of force majeure cannot be associated with *lex artis*, since the latter is not related to the rupture of the causal nexus, but to the legal duty that the legal system imposes on the individual to bear the damage caused by the Health Administration. This differentiation is evident in the development of Spanish case law with respect to HIV infections, which were initially considered as cases of force majeure because they were irresistible according to the state of knowledge at the time the damage was caused, and, since the rulings of the Supreme Court of 1 and 6 November 2001, have been considered as cases in which the unlawfulness of the damage is absent, since they are not external and independent of the risk caused by the health service.⁵⁶

Such considerations are important in damages caused by the use of AI, since such technology, as mentioned above, causes difficulties in determining whether the causes are external to the risk and the health service, being caused by errors made by manufacturers or programmers, or internal, being properly related to the Health Administration. Considering that, in the second case, if such causes are also undetermined or unknown, we would be facing a fortuitous event, for which the Health Administration would also be

⁵¹ *Ibidem*, 111.

⁵² O. Mir Puigpelat, *op. cit.*, 69.

⁵³ *Ibidem*, 225 - 250.

⁵⁴ COM (2022) 496 - Brussels, 28 September 2022.

⁵⁵ Spanish Supreme Court Ruling of 31 May 1999.

⁵⁶ A. L. Rivas López, *op. cit.*, 116.

responsible.⁵⁷

On the other hand, there are cases where the compensable damage is not caused by a single cause, but by several technically relevant causes. In these cases, case law applies the concurrence of causes and modulates the liability of the Public Administration, ordering it to pay the proportional part of the compensation.

The aforementioned figure can be useful in the field of IA, where the Health Administration proves that the damage was not exclusively caused by the provision of the public service, but that the relevant conduct of other operators, such as the programmer or manufacturer, also had an influence. In this sense, it should be the Health Administration that is obliged to demonstrate the confluence of different causes since, in cases where there is doubt as to whether it is the conduct of the Health Administration or of another operator that caused the damage, it would be advisable that the former should be liable for compensation.

4. The application of a strict liability regime to the use of artificial intelligence by the Health Administration

Article 32 LRJSP, by maintaining the sense of the previous legal provisions and prescribing that individuals have the right to be compensated for any injury resulting from the normal or abnormal operation of public services, evidently recognizes an absolute strict-liability regime that theoretically should not admit exceptions.⁵⁸ However, case law has found it necessary to impose limits such as the application of the state of knowledge or *lex artis*, which clearly prevent fault from being totally irrelevant in the analysis of the liability of the Health Administration and of the Public Administration in general.

In this way, it is evident that the elements of fault are introduced into the analysis, by the jurisprudence, using the requirement of the unlawfulness of the damage. This ambiguous requirement has caused enormous legal uncertainty to individuals and has been commonly applied to reject obvious liability of Public Administrations.

The problems that the unlawfulness of the injury has generated at the time of applying

the regime of liability of the Administration are not new but have existed since enactment of the regime in 1954. However, with the emergence of these new technologies, which can be used by the Administration to provide public services, the difficulties will surely increase if minimum predictability is not granted to the regime.

In this sense, the legal system should not only require that the legal duty of the individual to bear the damage is expressly prescribed in the Law, as is the case of *lex artis* and informed consent, but also that some of these criteria be specifically regulated for cases of liability for the use of artificial intelligence. Additional procedures and parameters should be established to adapt the criterion of the unlawfulness of the injury to the reality of new technologies.

On the other hand, the recognition of a global regime of liability, applicable to all administrative activity, cannot be the best option. Instead, what is clearly advisable is the recognition of a differentiated regime of subjective liability for certain areas of administrative activity and of strict liability for others. As established in the Artificial Intelligence Act, which determined a strict liability regime for the use of AI that generates high risk to users and a subjective regime for the use that generates low risk.

In the field of the use of AI by the Health Administration, the criterion of the specialists seems to coincide with the strict-liability regime currently in force in Spain. Firstly, because this type of liability was rightly developed, during the 19th century, as a response to the risks brought about by the new technological developments of the industrial revolution, which makes it ideal for the challenges posed by the use of AI, and, secondly, because it is difficult to determine the perpetrator of the negligent conduct when using this type of technology. So, it is convenient that this determination becomes irrelevant.⁵⁹

In this sense, the Report of the Group of Experts, while stressing the importance of the coexistence of liability regimes within each EU member, highlights an additional advantage of the application of a strict-liability regime to the use of emerging technologies. This type of liability spares the

⁵⁷ *Ibidem*, 113.

⁵⁸ O. Mir Puigpelat, *op. cit.*, 69.

⁵⁹ European Commission, *Report of the Expert Group on Liability and New Technologies*, 2019, 25.

victim the impossible task of identifying the breached standard of care, taking into consideration that standards of care were designed for human conduct.⁶⁰

On the other hand, as a disadvantage of the application of strict liability to the use of emerging technologies, specialists point out the impact that this recognition can have on their use and development. This consideration applied to the field of public healthcare may dissuade healthcare administrations from acquiring this type of tools, due to the risk represented using artificial intelligence and the high probability of being held liable for its use.

However, the consequences of applying a negligence-liability regime to the use of AI by the Health Administration may be greater, since in this case the individual would be discouraged from undergoing treatments or therapies that use artificial intelligence.

Therefore, a convenient solution is the one proposed by the theory of increased liability of the owner of a robot. This theory developed from the idea of the difficulty of proving the negligence of the owner, the defect of the product or the causal link, to subsequently conclude that the owner should be strictly liable for the damages caused to third parties, but with the recognition of a limit to such liability.

Applying this limit of liability to the Health Administration, which will generally own the robot or AI system, may avoid the deterrent effects mentioned above.

5. Conclusions

The use of systems or devices involving artificial intelligence by the Health Administration presents important additional challenges to the application of each of the requirements demanded by the liability regime provided in the Spanish legal system.

One of the main challenges is related to the diversity of the damages that these systems can generate and the application of the criterion provided in the first paragraph of article 34 of the Public Sector Legal Regime Law, related to the state of knowledge or *Lex Artis*, as a criterion to determine the unlawfulness of such damages. In this sense, in the field of the use of AI, the application of this criterion should be limited to protect the

rights and interests of individuals and to avoid contradictory judgments.

On the other hand, there are enormous challenges regarding the victim's burden of proof, which is extremely complicated in cases where the compensable injury is caused by the use of AI, as this technology is highly opaque, complex, open to new information and vulnerable to cyber-attacks. This is one of the areas where legislative reforms, such as those contained in the Proposal for a Directive on the adaptation of non-contractual civil liability rules to AI, are going to be extremely necessary. Considering also that the enactment of this proposal would oblige Member States to establish specific regulations in this area and to update or adjust their liability regimes to these types of technologies.

Likewise, it is essential to adopt reforms in the imputation of liability, such as the recognition of rebuttable presumptions regarding causality and negligence in the defendant's conduct. In addition to this, with the development of autonomous robots with strong artificial intelligence, it will become even more difficult to impute their actions to the Health Administration which currently only acts through its public servants.

Finally, as the use of artificial intelligence in the healthcare field is of high risk, the legislative initiatives of the European Union recommend the application of a strict-liability regime, like the one currently recognized in Spain. However, this liability regime is extremely deficient in providing criteria that guarantee objectivity and predictability in its application. These deficiencies will be aggravated when applied to cases where the use of artificial intelligence by the Public Administration causes damages to individuals, as the risks associated with the use of this type of technology are indeterminate and extremely difficult to assess.

The implementation of a strict-liability regime for this type of cases, from the point of view of supporting innovation, should be limited. This limitation aims to prevent the Health Administration from being discouraged in acquiring this type of technology for the provision of health services, which would unjustifiably deprive patients of the enormous advantages that its use represents.

⁶⁰ C. Gómez Liguerra and T. García-Micó, *op. cit.*, 505-506.

