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The Construction of the Theory of Informed Consent in Brazil: Analysis and Influences of the Trajectory in the United States and Spain for Brazilian Law

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Abstract

This article aims to present the institutional change in the doctor-patient relationship in Brazil through the historicity and course of patient autonomy through the theory of informed consent coined in the West, notably in the United States and Europe. It starts with a theoretical study from the perspective of the moral theory of informed consent and the right to privacy built through decisions of the United States courts and the dogmatics of informed consent in Spain to demonstrate, by the historical and bibliographic analysis on the subject, the influence they had on their adoption in Brazil, through the analysis of Brazilian norms and the jurisprudence of the Superior Court of Justice.

Keywords

Civil Law, Institutional Changes in Private Order, Theory of Informed Consent, Brazilian Jurisprudence

1. Introduction

Studies and reflections on health have achieved within the scope of Law a special evolution on patient protection (González León, 2009: p. 15). Over time these digressions followed the different paradigms that sought to define the relationship between doctor and patient or more broadly between health professionals and patient. If before this relationship was marked by a paternalistic aspect where the professional held the power, the art, and the technique in his legal position, today the treatment is in the sense of a balanced relationship between

rights and duties between both parties with special uplift of the rights and decision-making powers of patients (Lima, 2016: p. 4). Within this process of institutional change, the theory of informed consent emerged as a new paradigm to boost the traditional doctor-patient relationship.

Spatially situating this change, the institutes are discussed as they were built in the legal trajectory of the West. In this sense, the focus of the analysis starts from the way in which the idea of informed consent was coined in the United States and Europe and how the process of inserting this theory into the Brazilian legal system took place. And although legal traditions in the United States and Brazil differ in terms of the construction of dogmatics—that is for the U.S. through common law, where judicial decisions and jurisprudence are the main source of dogmatics and in Brazil centered on civil law whose written legislation is prominent—it was through the development of the theory of informed consent in U.S. jurisprudence that made possible the incorporation of the doctrine in Brazil, especially through judgments in Brazilian higher courts.

In legal terms there were two ways in which the institutional change towards patient autonomy emerged: one relating the patient's right to information and decision to a moral theory of informed consent and the other extracting the patient's informational autonomy from the to the right to privacy. Thus, the first chapter of this work will take care of a descriptive history of the process in the United States and Spain. For the analysis of these two aspects, Ruth R. Faden, Tom L. Beauchamp and Nancy King will be used as theoretical references in the writings on the decisions of the American courts on patient protection and informed consent in the book "A History and Theory of Informed Consent". González León, who brings the European perspective of informed consent from its construction in Spain, Antonio Seoane, who discusses the differences and confluences of the legal construction of patient autonomy in the United States and Spain, and Davinia Cadenas Osuna, who presents the theory informed consent through a comparative study between different orders of patient protection.

Along with the digression on the historicity and construction of the theory of informed consent in the second chapter it will seek to present the way in which the theory of informed consent was received in Brazil through the analysis of the legal acts that began to regulate the doctor-patient relationship and in the third chapter the way in which the theory has been inserted in the Brazilian legal system through its use in national jurisprudence through the analysis of judgments of the Superior Court of Justice of Brazil (*Superior Tribunal de Justiça—STJ*). The main objective of this work therefore is to demonstrate the theoretical path of the theory of informed consent that led to an institutional change in the doctor-patient relationship in Brazil.

For the purposes of this work the methodology used was the bibliographic research about informed consent in the United States, Spain and Brazil the analysis of the Law of the three countries from a comparative perspective of norms on informed consent and of jurisprudence left over. The theme in the legal systems

of the three countries with the objective deductively identifies the similarities, common origins, and differences between the three legal paths. The research used digital legislation research tools, articles in magazines published on the internet and the official portal for the dissemination of judgments of the STJ. The historical and systematic method was used as well for the exposition of ideas.

2. Historicity of the Evolution of Patient Autonomy Considering the Theory of Informed Consent and Privacy Protection

To begin the discussion on the historicity of the evolution of patient autonomy it is necessary to identify the way in which it was constructed in the legal tradition of the United States. In this tradition it is important to highlight the construction of a theory of informed consent which along with the development of the right to privacy represented the rise of the patient's autonomy in their relationship with a health professional. Indeed, it was through the decisions of the U.S. courts that informed consent was raised as a legal category to be valued by the civil system (Lima, 2016: p. 39).

The trajectory of the theory of informed consent involves an institutional change in the way the doctor-patient relationship is interpreted. If before this relationship was marked by a paternalistic aspect, in which the professional assumed a differentiated and prominent position in relation to art and technique in his legal position, today the key issues in the doctor-patient relationship are reciprocal trust and equalization of rights and duties between both parties with special enhancement of patients' rights and decision-making powers. The doctor's burden of informative duties increases. The establishment of informed consent as a requirement for the medical act involved the creation of a consensus on the need (the right) for the patient to have the possibility of consenting to the medical act after extensive information about the act itself, the risks and the consequences inherent to it and its alternatives.

Its establishment, as it is possible to suppose, was gradual, so the jurisprudential path could, over time, outline the requirements and characteristics of the theory as it is presented in the 21st century. At the same time the construction of the idea of informed consent was also developed in Europe through other movements originating, above all, in medical deontological guidelines and theoretical consensus produced on an international scale. In both cases, the idea of informed consent arose from two distinct strands of foundation, moral theory of informed consent and privacy protection.

2.1. The Evolution of Patient Autonomy in the United States: The Perspective of Informed Consent and the Right to Privacy

Ruth R. Faden, Tom L. Beauchamp and Nancy King outline in "A History of Informed Consent" that informed consent involves some analytical components, and that these components were brought together in what was agreed to be called the theory of informed consent. First, disclosure occurs, the patient rece-

ives full disclosure of information about an intervention, second of all a comprehension has to be established, which means the patient fully understands the intervention, then there is the voluntariness, the patient acts voluntarily by consenting without any type of coercion. Also, the patient must be fully competent to give consent. And finally consent needs to be given either orally or written. However, the construction of the theory occurred gradually in the United States mainly through judicial decisions, which will be analyzed below.

The authors start from the decision in the British case Slater v. Baker and Stapleton of 1767 as a remote antecedent of the theme, which, despite not having been issued in the United States and having had little influence on American decisions in the 19th century, is considered the most remote reference of a judicial decision in which the will of the patient was considered in the response to merit. In this case, doctors were convicted of refusing to remove dressings from a patient when she asked and still producing a fracture by experiencing unauthorized orthopedic treatment.[1]

Next, the authors present the case Carpenter v. Blake (1871) in which the court found negligent on the part of doctors the lack of information to the patient about the care and protections that needed to be taken in a postoperative period and the consent obtained for the continuity of the treatment was given through false information that the surgery was in the normal healing process. This case became emblematic because it is a hypothesis in which information, or the absence of it on the part of the medical team, was the main crux of the decision in a health care situation.[2]

While this decision was significant, it focused on patient information rather than patient consent. In this sense, the authors present the cases Mohr v. Williams (1905) where a surgeon was convicted of operating on the left ear on a patient who had only authorized the intervention on the right. The case of Pratt v. Davis (1906) in which a doctor performed a hysterectomy without the patient's specific authorization for such a procedure, she had authorized a previous intervention, but the court understood that there was no need to speak of implicit consent. And the case of Rolater v. Strain (1913) where the doctor extracted a bone extrapolating the limits of the patient's consent, she had authorized the procedure, but in a different way from the one performed by the doctor (Faden, Beauchamp, & King, 1986: pp. 122-123).

In these three cases the *ratio decidendi* of the courts focused on the harm caused to patients by the absence or defect in consent. In other words, it was decided that the harm perceived by patients is directly related to the need to obtain their consent for medical procedures. Furthermore, the fact that such decisions did not include consent as an integral part of the medical act, but linked them to the existence of proven harm, are crucially important as they place consent in a privileged position in the doctor-patient relationship.

The emblematic case that became a turning point in the way informed con-

[1]Slater v. Baker and Stapleton, 2 Wilson 359, 95 English Report 860, 1767.
[2]Carpenter v. Blake, 60 Barb 488, N. Y. Sup. Ct. 4th Dept. May 1, 1871.

sent theory would be treated was the so-called Schloendorff Case, or Schloendorff v. Society of New York Hospitals, 1914. In this case, a physician removed an abdominal tumor from a patient who had authorized only a diagnostic exploration and had expressly stated that she wanted the intervention to be limited to examination. The medical act, therefore, although it did not cause harm to the patient, was contrary to her previously expressed will.[3]

Here, the decision raises consent to an autonomous right of the patient that is independent of any other damage, and any procedure that is performed without it being collected is liable to compensation. The next step would be to make this consent informed.

The expression "informed consent", in turn, appeared in 1957 with the case of Salgo v. Leland Stanford Jr. University Board of Trustees where the court held that a radiologist's lack of information about the possible complications and secondary risks of an aortography is equivalent to hiding facts necessary for the formation of rational consent in relation to the proposed treatment (Faden, Beauchamp, & King, 1986: pp. 126-128). Information becomes one of the landmarks in the theory of consent, and the physician is responsible for this positive provision.

Following the post-Schloendorff cases, the theory of informed consent is gaining strength and is better described. With the case of Nathanson v. Kline of 1960, the Kansas Supreme Court established that information is not unlimited, but the physician must act and reasonably and sufficiently inform the patient so that he can make his decision (Faden, Beauchamp, & King, 1986: p. 130).

With the case of Berkey v. Anderson (1969) the court understood that the physician must assume that the patient has a layman's common knowledge in the matter and should treat the information differently from what he would treat with other professionals. In the case of Canterbury v. Spence (1972) the understanding was that it is the patient's needs that define the breadth of information the physician must provide, but from a reasonable point of view.[4]

All the judgments listed above correspond to the U.S. jurisprudential path that allowed the construction of the theory of informed consent based on a moral perspective of patient protection. However, the process of institutional change in the doctor-patient relationship in the United States also had another development path linked to the idea of patient autonomy and the right to privacy.

Regarding this second way, Professor José Antonio Seoane points out (Seoane, 2013: p. 18) that the idea of privacy in the United States originated in another right that already supported doctrinal recognition, which would be the right to intimacy or the right to be let alone, or the right to be left alone, coined by Judge Thomas M. Cooley (Cooley, 1879: p. 29) in 1879. It is also in this sense that, still in 1890, the authors Samuel D. Warren and Louis D. Brandeis published an article entitled The Right to Privacy in the Harvard Law Review. In this article, the

[3]Schloendorff v. The Society of New York Hospital, 211 N. Y. 125, 105 N. E. 92, 1914.
[4]Canterbury v. Spence, 464 F.2d. 772, 782 D. C. Cir., 1972.

jurists analyze some judgments in the United States that have given reason to the protection of works of art, lost personal letters and subtracted handwritings relating this protection to intellectual property. The authors, however, conclude that in most cases the fundamental protection principle would not be that of property per se, but rather of a broader right to protection of privacy (Warren & Brandeis, 1890: p. 205) or right to be let alone.

Although the doctrine already emanated voices on the law, it was only included in U.S. jurisprudence in 1967 with the case of Katz v. United States, where the United States Supreme Court, interpreting the Fourth Amendment to the Constitution (United States of America, 1792), ruled that the command to prevent search and seizure without warrant covers any situation in which people may have an expectation of privacy. In the present case, an individual had been accused by the FBI (Federal Bureau of Investigation) of transmitting illegal betting information by telephone, however, obtaining this information by the investigative body, without a specific warrant, infringed the individual's right to privacy[5].

After the jurisprudential establishment of a right to privacy based on the Constitution in the Fourth Amendment, its application in health relations was only a matter of time. In 1965, in Griswold v. Connecticut, the United States Supreme Court ruled that the Connecticut state law that prohibited the use of contraceptives violated the marital right to privacy enshrined in the provisions of the Bill of Rights and, therefore, The State could not prevent the search for medical advice and the use of contraceptives for violating a private sphere of decision of the couple[6]. In 1972, the same Court issued a decision in the case of Eisenstadt v. Baird, in favor of the use of contraceptives even for couples who were not married based on the Fourteenth Amendment equality clause and the right to privacy[7]. And in 1977, in the Carey v. Population Services International, it was established by the Supreme Court that a state could not place restrictions on the advertising, sale and distribution of contraceptives to individuals of any age, extending the right to privacy to all citizens including minors, in the decision, the Court rules including on the impossibility of the State to require parental consent for the decision of the minor.[8]

As demonstrated above, the path of institutional change in the doctor-patient relationship in the United States has developed both through the theory of informed consent and through the right to privacy. Although the perspective of privacy had a great influence on this movement, this is not the object of analysis of this article, that is why, from here on, the study will focus only on the development of the theory of informed consent.

2.2. The Theory of Informed Consent in Spain

A second niche for the development of the theory of informed consent as it is

[5]Katz v. United States, 389 U.S. 347, 1967.
[6]Griswold v. Connecticut, 381 U.S. 479, 1965.
[7]Eisenstadt v. Baird, 405 U.S. 438, 1972.
[8]Carey v. Population Services Int'l, 431 U.S. 678, 1977.

established in the West in this 21st century was Europe. Due to its continental nature and the plurality of legal systems and traditions that often do not resemble each other, a study of the influences of all Europe in the construction of a theory would be too laborious and impossible to conduct in an article-level work. In this sense, for this study, the option was to stick to a single country of civil law tradition, to contrast with the jurisprudential tradition of the United States.

The study of Spanish Law, as a European country with a Roman-Germanic tradition and which, due to its historical trajectory, projected and still maintains strong influences on Latin American Law, proves to be important for the next discussion that will be held below regarding the insertion of informed consent theory in Brazilian jurisprudence. In addition, the very characteristics of supra-state status of certain types of norms that inform the countries of the European Union, of which Spain is a part, make the study of the legal construction of a certain institute in this country a focal point that reverberates in the study of the legal construction of the entire block.

In this mission, the writings of José Antonio Seoane will be used as a reference, in the article *La construcción jurídica de la autonomía del paciente*, published in 2013 in the Spanish magazine EIDON, the central ideas of Carmén González León in the article *La proteccion del paciente y el consentimiento informado* published in 2009 in the Portuguese Journal of Health Law and by Davinia Cadenas Osuna in the book *El consentimiento informado y la responsabilidad médica* published in 2018 by the Boletín Oficial del Estado da Impressa Nacional da Espanha.

When analyzing the legal configuration of patient autonomy in Spain, Seoane points out some distinctive characteristics of the Spanish and American process. First, in Spain the construction of the idea of patient autonomy is much more recent and more compact than in the U.S. While in this one the discussion goes back to the 18th century, as already mentioned in the previous topic, in that one it focuses on little more than three decades of discussions.

This temporal proximity is responsible for the main characteristics of the Spanish process, which are grouped into 3 points: "1) The reflection of the transformation factors of contemporary legal systems" which lead to "constitutionalization, evident above all in the normative superiority of the constitution, in the constitutional jurisdiction and in the omnipresence of fundamental rights and the extrapolation of the State framework, in the form of supra-state through European, supra-state and international community norms and of infra-state through the regulations of the Autonomous Communities", also "2) A legislative construction, typical of a model of the Roman-German legal system characteristic of Continental Europe, completed with contributions from ordinary and constitutional jurisprudence", and last "3) The complementarity of two perspectives for understanding the configuration of autonomy: that of the patient or user, with the growing recognition of their autonomy and their rights, and that of

the assistance professional, in the thread of evolution and the notion of *lex artis"* (Seoane, 2013: p. 21).

From the first characteristic pointed out by Seoane, the Constitution played a prominent role in the construction of the idea of autonomy of patients, and here the reference is mainly to the exegesis of the fundamental rights inscribed in the Constitution of 1978. In addition, the extrapolation of the State made the legal tradition receive norms from sources outside the national production for the establishment of the institute. That is why so important in the European tradition were the international norms and, in the case of Spain, the Autonomous Communities to weave the theory of informed consent (España, 1978).

In fact, it was with the Spanish Constitution of 1978 that, through the provisions of its Art. 15, in the section on fundamental rights and public liberties and by guaranteeing the right to physical and moral integrity, brought to the constitutional level what would later be the foundation of patient autonomy. In addition to this article, arts. 10, 16, 17 and 18 also dealt with aspects involving life, personality, freedom of conscience and intimacy, which are also in the spectrum of rights that constitute the patient's autonomy.

In the context of pre-constitutional frameworks, it is necessary to mention the promulgation of the Nuremberg Code, in 1947, a product of the Nuremberg trials in the post-World War II period, as a response to the atrocities that occurred in the field of medical research during the period of the Nazi government. Central Europe, and that many of them were even financed by the US government (Osuna, 2018: p. 50) in a period when there was already a jurisprudential understanding of patients' rights as demonstrated in the previous topic. And, also, the Declaration of Helsinki, published in June 1964 by the World Medical Association as a product of the work of the 18th World Medical Assembly, a document that was embodied in the establishment, through 32 provisions of ethical principles for medical research in human beings.

It is important to emphasize that both the Nuremberg Code and the Declaration of Helsinki dealt mainly with research and not with medical intervention/health care in human beings, however their provisions served as a starting point for the development of other ethical standards in the field of medical practice. In fact, the Declaration of Helsinki in its original wording proposed a differentiated treatment between scientific experiments and therapeutic experiments, requiring the existence of mandatory prior consent of the patient only in the first (Osuna, 2018: p. 88).

It was in this sense that in 1981, the World Medical Association, promulgated the Lisbon Declaration on the Rights of the Patient, which had the power to systematize ethical norms both in the field of research and in the field of intervention and health care in general and establishing primarily the patient's right to self-determination.[9]

Patient autonomy was deepened with the signing of the Convention on

[9] *World Medical Association*, 1981, WMA Declaration of Lisbon on the rights of the patient.

Human Rights and Biomedicine of the Council of Europe (CDHB), in 1997, which came into force in Spain on January 1, 2000, and with the edition of Law 41/2002, of November 14, which became the Basic Law regulating patient autonomy and rights and obligations in informational matters and clinical documentation (LBAP or LAP).

The latter, the LBAP (and its later regulations such as Law 16/2003 on cohesion and quality of the National Health System (LCCSNS and Law 44/2003 on organization of health professions (LOPS)) is considered the most important and influential in the Spanish post-constitutional stage as it represented a regulation specifically aimed at patient autonomy as included in its Explanatory Memorandum (Seoane, 2013: p. 23).

Cármen González León also mentions the importance of the CDHB for Spanish law about patient rights (González León, 2009: p. 15). It can be seen, therefore, that the establishment of the theory of informed consent in Spain followed a path that began with the recognition of deontological and medical ethics norms and that culminated in the legislative sedimentation of the principle of informed consent through the LBAP, in a different path from the jurisprudential establishment from United States. With the enactment of a legislative diploma with a specific provision on informed consent, Spanish doctrine began to be concerned with the contours and requirements of informed consent, and it is in this sense that Davinia Cadenas Osuna points out as requirements of informed consent extracted from the LBAP liberality, voluntarism, intentionality, understanding and absence of external control (Osuna, 2018: pp. 267-268) and defines the institute as a very personal and fundamental right of the patient and the collection of consent as an integral part of the medical act.

Osuna advocates that informed consent can be defined as the very personal and fundamental right of the patient or client to decide autonomously, regarding any action in the field of their health, their submission or rejection of it. This decision must be made by the patient after interacting with the healthcare professional in a continuous dialogic process in which the latter must communicate and explain to the patient the information provided for in Article 4 LAP, sometimes requiring written proof of information and consent, although as an ad abundantiam requirement and, in no case, a substitute for the inexcusable informative dialogue that doctor and patient must maintain (Osuna, 2018: p. 504).

It's important to note that both the United States and Spain have complex healthcare systems, and the interpretation and application of informed consent may vary within different regions and healthcare institutions. Despite there are some differences between them, with the United States following the Common Law system and Spain adhering to the Civil Law tradition the legal framework and ethical considerations are vital components of patient protection in both jurisdictions. In the United States, informed consent is grounded in the principle of patient autonomy and is a cornerstone of medical ethics and law. The American legal system places a strong emphasis on the duty of healthcare providers to

obtain informed consent from patients before any medical treatment or procedure. This approach is largely derived from case law as it was shown. In Spain, the legal framework for informed consent is influenced by both national laws and European regulations as noted above. The informed consent process requires healthcare providers to inform patients about the nature of the proposed treatment, its risks and benefits, and any available alternatives. Patients are encouraged to actively participate in the decision-making process.

The history marked by both the legal trajectory of the United States and Spain shows that developments in legal systems have shaped changes in the relationship between doctor and patient. The insertion in the United States of the theory of informed consent through jurisprudential constructions and, through laws on health and patient protection in the case of Spain, reveal that the legal system was responsible for changes in the relationship between doctor and patient, placing the patient in a position of equality in relation to health professionals with rights related to their personality. The existence of an American jurisprudential tradition and a Spanish law that deals with the subject provide the points of comparison to study the way in which the theory of informed consent was established in Brazil. The next topic will explore how Brazil's legal system embraced the theory of informed consent through its jurisprudence to show that, although late, changes in the relationship between doctor and patient have also evolved.

3. The Theory of Informed Consent in Brazil

After discussing the construction of the theory of informed consent in the United States and Spain, this topic will analyze how the theory of informed consent was incorporated into Brazilian law through a descriptive study of the existing Brazilian norms on the subject and which will culminate, in the analysis, included in the third and last chapter of this article, of the presence of judges using informed consent as a reason to decide in the jurisprudence of the Superior Court of Justice (*Superior Tribunal de Justiça—STJ*), the Brazilian superior court on federal Law.

The Incorporation of the Theory of Informed Consent in Brazilian Law

In an opposite way to the American path, the first norms on informed consent in Brazil go back to the deontological provisions of professional bodies, such as the Brazilian Federal Council of Medicine, and general government norms on health in the second half of the 20th century, but as in Spain, the enactment of the Brazilian Federal Constitution in 1988 was a fundamental milestone in terms of protecting patients' rights and, consequently, incorporating the notion of informed consent in the legal relationship between doctor and patient.

In the doctrinal scope, José de Aguiar Dias, a Brazilian jurist, already wrote in 1950 in the field of Civil Liability about the responsibility of the medical professional to obtain the patient's consent in the face of a risky operation or treatment

and not only a simple consent, but a free and informed acquiescence (Dias, 1950: p. 262). In 1975, the Federal Council of Medicine of Brazil (CFM) published Resolution CFM n˚ 75, starting to expressly adopt the Declaration of Helsinki in the scope of clinical research, and which, among other provisions, contained specific mention of the need to obtain the patient's consent after due explanation about the therapeutic procedures that should be adopted (Brasil, 1975).

With the promulgation of the Federal Constitution of 1988 and the vast foreshortening of fundamental rights, especially the dignity of the human person (art. 1, III) and the Right to health (art. 6, caput, and art. 196), the notion of consent gained space for its expansion and further development in the country (Lima, 2017: p. 21). Indeed, the Magna Carta does not contain any specific provision on the subject, in fact, the term "consent" is only mentioned once throughout the entire constitutional text in item XI of article 5 on inviolability of domicile (Brasil, 1988). Although it is possible to establish a relationship between home and body for the purpose of defining consent and inviolability of this or that, this was not the path followed by legislation to consolidate the theory of informed consent.

In another dimension, the Consumer Defense Code, Law 8078, of September 11, 1990, also known as CDC, an instrument published two years after the last Brazilian constitution, is considered a legislative and interpretative landmark in the theory of informed consent in Brazil. It is in this line of thought that Professor Cláudia Lima Marques, in an important article published in Revista dos Tribunais in 2004 and entitled "A responsabilidade dos médicos e do hospital por falha no dever de informar ao consumidor", argues that Brazilian law applies that code in doctor-patient relationships (Marques, 2004: p. 11).

The use of the CDC in doctor-patient relationships had also been applied by the courts at the beginning of the millennium. Also in 2004, the Superior Court of Justice, considering Special Appeal No. 419,026, reported by Minister Carlos Alberto Menezes Direito, on the civil liability of the hospital and the doctor for forgetting a foreign body in the body of a patient after cesarean section, and based on the CDC, decided for the joint and several liability of both.[10]

The great importance of this interpretive position in the context of informed consent in Brazil is that, because of the recognition of the application of the CDC to doctor-patient relationships, the enormous burden of informative and care duties required for the service provider applies to the medical professional within the scope of healthcare provision. The Consumer Defense Code is a legislation full of devices with an ostensibly protective character to the weak part of the relationship, as its own name claims, so the patient resorts to all of them (Brasil, 1990). And as for the liability regime imposed on suppliers regarding the deficiency in information about the service, arts. 12 and 14 provide for specific liability, regardless of fault, in case of damages resulting from insufficient or in-

[10]*Superior Tribunal de Justiça*, REsp 419026/DF RECURSO ESPECIAL 2002/0027101-3, Voto da Ministra Nancy Andrighi, data de julgamento: 26/10/2004, DJ 21/02/2005 p. 169, RDR vol. 31 p. 410, RSTJ vol. 201 p. 297.

adequate information about the use and risks of products or services, whereas §4 of Art. 14, when dealing with the responsibility of the liberal professional, even though it takes place in a subjective way, with the verification of guilt (Brasil, 1990). It is through the fulfillment of informative duties and obtaining the patient's informed consent that the professional is protected from possible liability, however, for Professor Bruno Miragem, the professional is only exempt from the damages resulting from the involuntary risks caused by the treatment or medical procedures which the consent was obtained, not exempting the professional from blame for the acts practiced in the strict sense (Miragem, 2015: p. 587).

Despite the recognition of its application in doctor-patient relationships, the CDC does not provide any specific provision on informed consent. In the wake of the Federal Constitution, the word "consent", much less the expression "informed consent" are not mentioned in any article of the diploma. Perhaps the device that could most resemble the idea of informed consent would be the one provided for in art. 39 which lists the performance of services without the express authorization of the consumer as an abusive practice by the supplier.

However, in addition to the wording providing for a reservation for "previous practices between the parties", which does not fit the informed consent regime, the device does not have the characteristic of information to qualify consent (or, authorization, as it is essay).

The Brazilian Civil Code, Law 10,406 of January 10, 2002, which replaced the previous codification of 1916, was also one of the legal frameworks that strengthened the patient protection system in Brazil. Analyzing the anatomy of the novel diploma, one can already see that the rights of the personality start to be regulated in more articles in relation to the 1916 Code and the tonic of the protection of the person adapts to the constitutional dictates of 1988 and, with regard bring express provisions related to physical integrity. to the protection of the patient, articles 13 and 15 bring express provisions related to physical integrity.

Such devices enshrine the principle of self-determination and the patient's right to dispose of their own body, themes that underlie consent in Brazil. The current Civil Code, in its art. 21 also brings a provision on privacy, establishing that "The private life of the natural person is inviolable, and the judge, at the request of the interested party, will adopt the necessary measures to prevent or stop an act contrary to this norm" (Brasil, 2002). It is important to mention that, despite the right to privacy having been, in the American trajectory, one of the main sources for the development of the theory of informed consent, in Brazil, however, it had only a secondary role.

Tangentially, the term informed consent was inserted into Brazilian legislation through Decree n˚ 5006, of March 8, 2004, which ratified and promulgated the Optional Protocol to the Convention on the Rights of the Child on the involvement of children in armed conflicts (Brasil, 2004), and in the context of protecting internet users, the term informed consent was inserted as a right in article 7, VII of Law 12,965 of April 23, 2014 (Brasil, 2014), this regulation, although it

does not contain provisions on health and patients' rights, brings up informed consent as a principle for data processing in general on the internet. And in 2018, with the publication of Law 13,709, the General Law for the Protection of Personal Data, there was the delimitation of a specific legal regime for health data, demarcating them as sensitive and inserting the duty to obtain informed consent as a requirement for your treatment (Brasil, 2018).

In the specific area of the right to health, Decree No. 7958, of March 13, 2013, dealing with guidelines for care for victims of sexual violence by public security professionals and the Unified Health System, established that SUS health professionals should collect the Informed Consent Form, signed by the victim and legal guardian, when assisting victims of sexual violence to collect traces to be forwarded to the official forensic examination (Brasil, 2013). Law 13,146, of July 6, 2015, which established the Statute of Persons with Disabilities, is also an important diploma on the subject, as it recognizes the right to self-determination in terms of capacity to consent to persons with disabilities, providing in its articles 11 and 12 the need to obtain prior, free and informed consent to carry out any treatment, procedure, hospitalization and scientific research (Brasil, 2015).

In summary, there is no specific regulation in Brazil on informed consent, the norms extracted for the subject are made through the exegesis of the Federal Constitution, the Consumer Defense Code, and the Civil Code, in addition to specific norms on topics different from the medical relationship -patient as data protection Informed and care for victims of sexual violence. Éfren Lima comes to this conclusion, citing the Family Planning Law (Law No. 9,263, of January 12, 1996) and the Organ Transplant Law (Law No. 9434, of February 4, 1997) (Lima, 2017: p. 64).

4. Consent in the Jurisprudence of the Brazilian Superior Court of Justice

In this last chapter, the objective will be to present how the theory of informed consent has penetrated Brazilian jurisprudence through the research and description of judgments of the Superior Court of Justice (STJ) that refer to the expression "informed consent". The STJ was chosen because the proposed study eminently involves a subject of civil law, a matter of exclusive competence of the Union in accordance with the constitutional provision, this being the court responsible for standardizing the interpretation of federal law in the country. In this attempt, of a more instrumental nature, the jurisprudence search tool available on the website of the analyzed court was used and the identification of the theory in the judgment or in any of the votes that composed the decisions.

Informed Consent in the Jurisprudence of the Superior Court of Justice: Judgment Research and Analysis

For the research of jurisprudence in the Superior Court of Justice (STJ), the tool "jurisprudence" available on the court's website https://scon.stj.jus.br/SCON/ was used. This tool makes it possible to search for terms and expressions contained

in the judgments by typing in a specific field. With the objective of identifying the penetration of the theory of informed consent in Brazil as it developed in Spain and the United States, we chose to research the exact terms as they appear in the doctrine used in this work. The technique was used to search between quotation marks for the term "informed consent", allowing the tool to present only those judged that contained the entire expression, that is, excluding those that only had "consent" or just "informed" separately. The research returned the following amount of data: 14 judgments, 447 monocratic decisions, 1 summary and 6 jurisprudence reports. With the aim of reducing the research object, the analysis will be limited to the rulings of the Superior Court of Justice, not focusing on monocratic decisions, jurisprudence reports and possible summaries. Based on the information obtained as a result of the research on the website, it was possible to put together the following table in chronological order by judgment: (Table 1)

Of the fourteen judgments, eight of them[11] use the expression informed consent specifically within the scope of the right to health in the process of patient autonomy and as a requirement of the medical act, in the other six judgments[12] the term is used as a general requirement of the consumer relationship (not dealing specifically with the doctor-patient relationship) and in compliance with the principle of transparency of Art. 6, III of the CDC as a corollary of the right to information.

As had already been demonstrated, the theory of informed consent had a late insertion in Brazil, having greater influence after the promulgation of the Federal Constitution of 1988, the data in the table above corroborate the same conclusion. The discussion on informed consent was first mentioned in the STJ trial only in 2002. The presence of the expression "informed consent" in monocratic decisions is even later, having been the first mention in REsp 653078, by the Rapporteurship of Minister Luiz Fux with judgment date on 08/23/2005, according to the search result screen.

The oldest judgment, REsp n. 436.827/SP of 2002, this is a lawsuit filed by a patient who, after having lost her vision, sought care from two medical professionals with the objective of performing surgery to restore her sight, there were several complications during the surgery and in the end there was no recovery. of vision. The patient then went to court on the grounds that the doctors had not informed her about the risks of the procedure and that, therefore, she was not able to adequately consent to the procedure. The ministers confirmed the patient's right and held doctors responsible for negligence in their professional practice.[13]

[11]HC 779289/DF, REsp 1848862/RN, REsp 1808050/SP, REsp 1540580/DF, REsp 985888/SP, REsp 1180815/MG, REsp 467878/RJ and REsp 436827/SP.

[12]REsp 1794971/SP, REsp 1540566/SC, REsp 1365609/SP, REsp 1121275/SP, REsp 1144840/SP and REsp 976836/RS.

[13]*Superior Tribunal De Justiça*, REsp n. 436.827/SP, relator Ministro Ruy Rosado de Aguiar, Quarta Turma, julgado em 1.10.2002, DJ de 18.11.2002, p. 228.

Table 1. Judgements about informed consent in Brazilian Superior Court of Justice.

Process	Reporter	Judging Body	Trial Date
HC 779289/DF HABEAS CORPUS 2022/0335886-0	Minister REYNALDO SOARES DA FONSECA	T5 - QUINTA TURMA	22/11/2022
REsp 1848862/RN RECURSO ESPECIAL (Special Appeal) 2018/0268921-9	Minister MARCO AURÉLIO BELLIZZE	T3 - TERCEIRA TURMA	05/04/2022
REsp 1808050/SP RECURSO ESPECIAL (Special Appeal) 2019/0097921-3	Minister NANCY ANDRIGHI	T3 - TERCEIRA TURMA	17/11/2020
REsp 1794971/SP RECURSO ESPECIAL (Special Appeal) 2019/0006347-2	Minister HERMAN BENJAMIN	T2 - SEGUNDA TURMA	10/03/2020
REsp 1540566/SC RECURSO ESPECIAL (Special Appeal) 2015/0154209-2	Minister NANCY ANDRIGHI	T3 - TERCEIRA TURMA	11/09/2018
REsp 1540580/DF RECURSO ESPECIAL (Special Appeal) 2015/0155174-9	Minister LÁZARO GUIMARÃES (DESEMBARGADOR CONVOCADO DO TRF 5ª REGIÃO)	T4 - QUARTA TURMA	02/08/2018
REsp 1365609/SP RECURSO ESPECIAL (Special Appeal) 2011/0105689-3	Minister LUIS FELIPE SALOMÃO	T4 - QUARTA TURMA	28/04/2015
REsp 1121275/SP RECURSO ESPECIAL (Special Appeal) 2009/0019668-6	Minister NANCY ANDRIGHI	T3 - TERCEIRA TURMA	27/03/2012
REsp 1144840/SP RECURSO ESPECIAL (Special Appeal) 2009/0184212-1	Minister NANCY ANDRIGHI	T3 - TERCEIRA TURMA	20/03/2012
REsp 985888/SP RECURSO ESPECIAL (Special Appeal) 2007/0088776-1	Minister LUIS FELIPE SALOMÃO	T4 - QUARTA TURMA	16/02/2012
REsp 976836/RS RECURSO ESPECIAL (Special Appeal) 2007/0187370-6	Minister LUIZ FUX	S1 - PRIMEIRA SEÇÃO	25/08/2010
REsp 1180815/MG RECURSO ESPECIAL (Special Appeal) 2010/0025531-0	Minister NANCY ANDRIGHI	T3 - TERCEIRA TURMA	19/08/2010
REsp 467878/RJ RECURSO ESPECIAL (Special Appeal) 2002/0127403-7	Minister RUY ROSADO DE AGUIAR	T4 - QUARTA TURMA	05/12/2002
REsp 436827/SP RECURSO ESPECIAL (Special Appeal) 2002/0025859-5	Minister RUY ROSADO DE AGUIAR	T4 - QUARTA TURMA	01/10/2002

The reasoning of the decision is through the idea that the absence of informed consent was embodied in medical malpraxis, therefore, causing civil liability based on art. 1545 of the Civil Code of 1916 (Brasil, 1916).

The other judgments, to a lesser or greater extent, will base their decision for the application of the theory of informed consent sometimes in the Consumer Defense Code[14], sometimes in Civil Code[15], sometimes in deontological norms[16], sometimes in more than one of these norms[17], which confirms in these diplomas the demonstrated source of the theory in Brazil.

In Habeas Corpus 779289/DF, the most recent ruling found in the research, in which the matter discussed is the possibility of medicinal use of cannabis for health treatment, the term "informed consent" refers to a requirement demanded by the National Surveillance Agency To obtain authorization to use marijuana for therapeutic use, the entire text of the ruling mentions the requirement for the "Patient Informed Consent Form". This decision allows us to infer that the analyzed theory was in fact established in the country with the respective instrumentalization of a term and its inclusion as a requirement to obtain such a substance.

5. Conclusion

In this article, the historical contours of the process of institutional change in the doctor-patient relationship were delimited. The outlines were traced in view of the legal trajectory of the United States of America in the development of a theory of informed consent and the right to privacy and the inclusion of the theory of informed consent in Europe from Spain. It is concluded that the American process followed a jurisprudential path and the Spanish process took place through the recognition of deontological norms, the Constitution and the establishment of specific legislation on the subject. In the last chapter, an outline of the late establishment of the theory of informed consent in Brazil from the 1988 Constitution, the Consumer Defense Code and the Civil Code was presented, not presenting specific legislation on the subject. And finally, the presence of the theory of informed consent in the decisions of the Federal Supreme Court and the Superior Court of Justice was empirically presented. From the study, the theory of informed consent as constructed in the United States and Spain had a lot of influence in Brazil and, despite the lack of specific normative sources, it has already been used in the jurisprudence of the Superior Court of Justice, which withdrew the validity of the theory in the cited norms.

[14] *Superior Tribunal De Justiça*, REsp n. 467.878/RJ, relator Ministro Ruy Rosado de Aguiar, Quarta Turma, julgado em 5/12/2002, DJ de 10/2/2003, p. 222.

[15] *Superior Tribunal De Justiça*, REsp n. 1.808.050/SP, relatora Ministra Nancy Andrighi, Terceira Turma, julgado em 17/11/2020, DJe de 26/11/2020.

[16] *Superior Tribunal De Justiça*, REsp n. 1.848.862/RN, relator Ministro Marco Aurélio Bellizze, Terceira Turma, julgado em 5/4/2022, DJe de 8/4/2022.

[17] *Superior Tribunal De Justiça*, REsp n. 1.180.815/MG, relatora Ministra Nancy Andrighi, Terceira Turma, julgado em 19/8/2010, DJe de 26/8/2010; *Superior Tribunal De Justiça*, REsp n. 985.888/SP, relator Ministro Luis Felipe Salomão, Quarta Turma, julgado em 16/2/2012, DJe de 13/3/2012; e *Superior Tribunal De Justiça*, REsp n. 1.540.580/DF, relator Ministro Lázaro Guimarães (Desembargador Convocado do TRF 5ª Região), relator para acórdão Ministro Luis Felipe Salomão, Quarta Turma, julgado em 2/8/2018, DJe de 4/9/2018.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

References

Brasil (1916). *Lei n˚ 3.071, de 1˚ de janeiro de 1916. Código Civil dos Estados Unidos do Brasil*. Presidência da República.

Brasil (1975). *Resolução CFM nº 671/75. Conselho Federal de Medicina*. https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/1975/671

Brasil (1988). *Constituição da República Federativa do Brasil de 1988.* Presidência da República. https://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm

Brasil (1990). *Lei 8.078, de 11 de setembro de 1990. Dispõe sobre a proteção do consumidor e dá outras providências.* Presidência da República. http://www.planalto.gov.br/ccivil_03/leis/l8078compilado.htm

Brasil (2002). *Lei N˚ 10.406, de 10 de janeiro de 2002. Institui o Código Civil*. Presidência da República. http://www.planalto.gov.br/ccivil_03/leis/2002/l10406compilada.htm

Brasil (2004). *Decreto n˚ 5.006, de 8 de março de 2004. Promulga o Protocolo Facultativo à Convenção sobre os Direitos da Criança relativo ao envolvimento de crianças em conflitos armados*. Presidência da República. https://www.planalto.gov.br/ccivil_03/_ato2004-2006/2004/decreto/d5006.htm

Brasil (2013). *Decreto N˚ 7958, de 13 de março de 2013. Estabelece diretrizes para o atendimento às vítimas de violência sexual pelos profissionais de segurança pública e da rede de atendimento do Sistema Único de Saúde*. Presidência da República. https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2013/decreto/d7958.htm

Brasil (2014). *Lei N˚ 12.965, de 23 de abril de 2014. Estabelece princípios, garantias, direitos e deveres para o uso da Internet no Brasil*. Presidência da República. http://www.planalto.gov.br/ccivil_03/_ato2011-2014/2014/lei/l12965.htm

Brasil (2015). *Lei N˚ 13.146, de 6 de julho de 2015. Institui a Lei Brasileira de Inclusão da Pessoa com Deficiência (Estatuto da Pessoa com Deficiência).* Presidência da República. http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13146.htm

Brasil (2018). *Lei N˚ 13.709, de 14 de agosto de 2018. Lei Geral de Proteção de Dados Pessoais (LGPD).* Presidência da República. http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm

Cooley, T. M (1879). *A Treatise on the Law of Torts or the Wrongs Which Arise Independent of Contract*. Callaghan and Company. https://repository.law.umich.edu/books/11/

Dias, J. A. (1950). *Da responsabilidade Civil* (2nd ed., v. I, v. II). Forense.

España (1978). *Constitución Española de 1978*. https://www.boe.es/buscar/act.php?id=BOE-A-1978-31229

Faden, R. R., Beauchamp, T. L., & King, N. M. P. (1986). *A History and Theory of Informed Consent*. Oxford University Press.

González León, C. (2009). La proteccion del paciente y el consentimiento informado. *Revista Portuguesa de Direito da Saúde. Separata de Lex Medicinae, 6,* 15-32.

Lima, É. P. P. S. (2016). El desarrollo histórico del consentimiento informado en España y en Brasil. *Civilistica.com, Rio de Janeiro, 5,* 1-34. https://civilistica.emnuvens.com.br/redc/article/view/623

Lima, É. P. P. S. (2017). *El Consentimiento Informado: Estudio Comparativo de los*

Sistemas Español e Brasileño de Protección al Paciente. Ratio Legis Ediciones.

Marques, C. L. (2004). A responsabilidade dos médicos e do hospital por falha no dever de informar ao consumidor. *Revista dos Tribunais, São Paulo, 827,* 11-48.

Miragem, B. (2015). *Direito Civil: Responsabilidade Civil*. Saraiva.

Osuna, D. C. (2018). *El consentimiento informado y la responsabilidad médica*. Boletín Oficial del Estado. https://www.boe.es/biblioteca_juridica/abrir_pdf.php?id=PUB-PR-2018-83

Seoane, J. A. (2013). La construcción jurídica de la autonomía del paciente. *EIDON, 39,* 13-34.

United States of America (1792). *Fourth Amendment to the United States Constitution*. https://constitution.congress.gov/constitution/amendment-4/

Warren, S. D., & Brandeis, L. D. (1890). The Right to Privacy. *Harvard Law Review, 4,* 193-220. https://www.cs.cornell.edu/~shmat/courses/cs5436/warren-brandeis.pdf

World Medical Association (1981). *WMA Declaration of Lisbon on the Rights of the Patient*. Lisbon.