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The irrelevance of informed consent in the medical liability lawsuit. An analysis of the civilian and state experience in Colombia

La irrelevancia del consentimiento informado en los litigios de responsabilidad médica. Un análisis de la experiencia civil y estatal en Colombia

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ABSTRACT: This research provides a general review of medical liability in the Colombian experience, specifically based on the jurisprudence of the Civil Chamber of the Supreme Court of Justice and the Third Section of the Council of State. All the above, intend to raise a critique of the irrelevance of the figure of informed consent in the liability trial, a matter that reconsiders some of the basic assumptions for the emergence of an indemnity obligation in the field of medical liability.

KEYWORDS: Medical liability, Civil Law, Administrative Law, Informed Consent.

RESUMEN: Este artículo ofrece una revisión general de la responsabilidad médica en la experiencia colombiana, específicamente, a partir de la jurisprudencia de la Corte Suprema de Justicia y del Consejo de Estado. Todo lo anterior, para plantear una crítica a la irrelevancia de la figura del consentimiento informado en el juicio de responsabilidad,

cuestión que replantea algunos de los supuestos básicos para el surgimiento de una obligación indemnizatoria en materia de responsabilidad médica.

PALABRAS CLAVE: Responsabilidad Médica, Derecho Civil, Derecho Administrativo, Consentimiento Informado.

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"There is no light without shadow in the human being".
Carl Gustav Jung

INTRODUCTION

Civil and State liability, with its different developments, regimes, and applications, is one of the broadest areas within the legal world, which is only natural, since determining why and to what extent damage is attributable to a subject requires a judicious and detailed argumentative content, which for each case is accompanied by several particularities (Mazeaud, 1983). In fact, within this area, several sub-areas have been formed, including medical liability (Giraldo, 2018, pp. 37-53).

Medical liability is an issue of great relevance in legal terms, provided that, to date, it has managed to capture the attention of two jurisdictions: the civil and the contentious-administrative. From there, several rulings have been issued that postulate jurisprudential lines in procedural and substantive aspects.

However, the experience of each of the jurisdictions has not been uniform, since there are several nuances in this respect, so much so that the Supreme Court of Justice considers that medical civil liability is contractual in origin, but the Council of State considers that the medical liability

of the State is non-contractual, matters that provide quite different perspectives concerning the lawsuit that gives rise to the indemnification obligation.

However, this is an issue that must be approached with caution and attention, not only because the issues involved are scattered in jurisprudence, laws, decrees, and resolutions, but also because the profession of medicine and its practice is related to the life and physical integrity of all persons who, at any time, have required or will require health care services, be they private or public.

Thus, the purpose of this journal article is to provide the reader with a comparative analysis of the civil and administrative experience in the field of medical liability, considering the most important particularities that each of these offers. Now, given that the complexity of the subject is considerable, we will first deal with the medical-health activity as a case of civil and State liability, and then make some criticisms about the irrelevance of informed consent in the liability trial, a matter that questions some of the fundamental assumptions of medical liability.

Before starting with the object of the journal article, it is important to specify that the present work will start from the assumption that the origin of a compensation obligation comes from the proof of damage, imputation, and basis or attribution factor. Where the first of these refers to the affectation, patrimonial or extramatrimonial, suffered by a subject. The second, imputation, is the relationship of causality, factual or normative, that exists between the conduct of the agent and the damage suffered by the victim. And finally, the basis or attribution factor is the category that allows the evaluation or qualification of the agent's conduct, which can be subjective or objective. The subjective factor consists of

fault, which, in contractual matters, constitutes a breach and, in non-contractual matters, the non-observance of an objective duty of care, diligence, or expertise. Additionally, the objective factor deals with the exercise of dangerous activities, which is concretised by the execution of activities that increase the normal levels of risk.

Having said the above, the present lines will set out the main points that must be considered for an indemnity obligation to arise in terms of medical liability, complemented by a critique that seeks to reconsider some of the assumptions explained, to offer effective protection to the right to self-determination of all persons who seek health care services.

1. MEDICAL-HEALTHCARE ACTIVITY AS A CASE OF CIVIL AND STATE LIABILITY

Within civil and state liability, few factual assumptions have managed to encompass the multiplicity of debates that medical-health activity generates and has generated. This subject is worthy of work and development by the legal academy, not only because of the large number of cases that are brought before judges, magistrates, and councillors, but also because of the significance and usefulness of the medical profession in society. Thus, Liability Law aims to design models of justice that respond adequately to the dynamics of medical services, which, day by day, requires more sophisticated knowledge and arguments to provide solutions to the legal problems generated by the damage caused to pre-patients and patients, who are the object of preventive, diagnostic and treatment measures.

In this section, we will study medical liability as a special area within the law, which aims to correct, via reparation and compensation (Díez-Picazo, 2001, pp. 312-

314), those injustices produced by the activity of doctors and health systems. Thus, for the present, the figure of the patient gains indisputable relevance, since he is constituted, together with his heirs - where applicable - as the direct victim of the medical negligence, so that, in this case, he is the procedural subject through which the trial of liability is triggered, which, will always be the plaintiff. Now, the same does not happen when we refer to the passive party of the litigation, since in the case of Colombia, it may well be a health professional (general practitioner or internist, surgeon, anaesthetist, nurse, etc.), a Health Provider Institute (IPS), a Health Promoting Entity (EPS)[1] or, in the case of State liability, a State Social Entity (ESE) that directly provides the health service.

The main particularity that characterises medical liability is that which is related to the practice of medicine itself, understood as a professional activity that is regulated by the legal system and whose purpose is, in general terms, to improve, alleviate or cure the illnesses of human beings. However, this does not indicate that the laws, decrees, or resolutions of the health sector make it possible to conclude when a doctor, an insurer, or a medical services entity is liable for an injury. The difficulty of the issue lies in the imputation and the grounds or attribution factors of the liability judgment.

Concerning imputation, the problem lies in something quite evident, this has to do with the set of factual situations that give rise to the damage, since in medical liability cases there are always two conditions (Honoré, 2013, pp. 1075-1085) that play the causal role: the illness and the doctor's activity (Perin,

1 Regarding the regulation of health in Colombia, especially the requirements for licensing, authorisation, and obligations of the entities in the sector, it is important to review the regulations: Law 1164 of 2007, the Single Decree 780 of 2018, and the Resolutions of the Ministry of Health and Social Protection.

2020, pp. 221-228). However, it is important to clarify that this is a practical problem so that the doctrine has not created new categories to talk about normative or causal imputation in matters of medical liability, for which the traditional models have been useful.

On the other hand, when it comes to the question of the grounds or, as they are also called, attribution factors, the professional fault is the central point of the problem, insofar as patients, lawyers and judges do not have the necessary knowledge to determine what is considered good or bad behaviour in the medical profession, among other things, because this is one of the most complex sciences within human knowledge and it is developing day by day. As is the case in the legal world, there may be different positions within medicine as to the best treatment for a given pathology, as we all know, medicine is not an exact science.

Now, to determine that a subject has acted with guilt, it is indispensable to have an idea or concept of what is not guilty, for which there are the archetypes of "a good father of a family" or "a good businessman", which provide a standard idea of what is understood by care, diligence, prudence, and expertise. However, guilt in the medical profession is not something that is exhausted by an archetype; the technicality of the profession requires a more sophisticated concept. For this reason, the parameter of non-culpability in medical liability is to be found in the *duty to be* of the professional technique, i.e., the *lex artis*, from which it is possible to deduce the minimum level of care, diligence, expertise, and prudence that any act of prevention, diagnosis, and treatment must-have.

The *lex artis* is characterised by its dynamism, since medical science, for each specific moment and case, may be

different. For this reason, its study requires a retrospective analysis that responds to the conditions of time, manner, and place in which a certain medical service occurred, which prevents the judge from considering a health professional or entity negligent based on the scientific knowledge that arose after the time when the facts occurred. Thus, the *lex artis* that is studied in each case is known as *ad hoc*, which is composed of the set of usages, customs, and practices applicable at a specific time and individualised to the pathological conditions of a given patient (De las Huertas, 2005, p. 22).

However, the professional negligence of the doctor or the health institutions can be evidenced not only in a lack of technical knowledge but also, for example, in the non-performance of medical services or the late performance of the same, the latter cases, unfortunately, being quite frequent in the Colombian experience. In that order, by way of explanation, but not exhaustive, medical fault can occur due to the non-provision of the service, having the obligation to do so, due to the late provision of the same, or due to a defective diagnosis or treatment (De las Huertas, 2005, p. 24). The above, considering that, in most cases, if not almost all, the obligations of doctors are of means and not of result, a matter that will be dealt with later.

Now, within the particularities of fault as a basis or attribution factor, it is important to mention that it can be generic or specific. The former occurs when the agent disregards a generic duty that is mandatory for all persons, and the latter when a particular or specific duty of a certain trade or profession is disregarded (Guido, 2015, pp. 100-105). Well, in the case of medical negligence, the specific fault is quite relevant, if there are many guidelines and precepts applicable

to this profession, including international conventions, laws, decrees, resolutions, guidelines, principles, codes of ethics, etc. In this regard, there is the international Convention on Human Rights and Biomedicine - the Oviedo Convention - which, in its article 4, enshrines the obligations of professionals, indicating that all medical interventions must comply with the applicable standards of conduct and regulations. In turn, Article 2 recognises the human being as a subject of prevailing interest vis-à-vis society and science, and article 3 determines that all persons shall have equal access to the benefits of health care (Council of Europe, 1999).

As far as the Colombian legal system is concerned, it is essential to refer to Article 26 of Law 1164 of 2007, which, in paragraphs 1 and 5, establishes that health professionals must act in a respectful, ethical and competent manner, seeking the greatest benefit for users. In addition, professionals must respect the limits of the Codes of Ethics, which are issued by the Ministry of Health and Social Protection (Trujillo and Patiño, 2019, pp. 21-36; Gómez, 2020)[2] . Additionally, there are

2 At this point it is important to make a caveat, at the time of writing, the world is facing one of the most important problems in public health, the SARS-COV 2 virus that leads to the COVID 19 pathology, which has generated high levels of hospital occupancy, So much so that the National Government, employing Legislative Decree 538 of 2020, granted the territorial authorities the possibility of taking control of the supply and availability of intermediate and intensive care beds in the IPS, intending to maintain an efficient administration of these resources. In addition, the Ministry of Health and Social Protection issued a document on *General recommendations for ethical decision-making in health services during the COVID-19 pandemic*. As we can see, this series of events has had the effect of changing the models of care, as long as health care systems have traditionally focused on patient-by-patient care, but this situation has proposed - in an obligatory manner - a new paradigm where it is essential to change the perspective of individual pathology for epidemiological systems so that it is possible to respond to the health needs of the so-called "new normality". Consequently, the prevalence of the individual over societies, a precept proclaimed by the Oviedo Convention, is a principle that under current conditions is not being comprehensively protected.

also other applicable regulatory bodies, such as Law 23 of 1981, the Single Decree 780 of 2016, and other administrative acts issued by the National Government.

Up to this point, we have already referred to *lex artis* based on the doctrine and applicable rules. Thus, to understand what has been explained in greater depth, we will now refer to case law, to identify how this concept is constructed in the courts.

First, we will review the case-law of the Civil Chamber of the Supreme Court of Justice, which, in a judgment of 12 January 2018 (C. S. J., Civil Chamber, SC 003-2018, 2018), studied a case in which the medical fault of a health service provider was disputed, due to an error of assessment. The facts of the case were that an entity had misdiagnosed the plaintiff since she initially went to the health centre with a headache, which was the result of an anxiety attack, for which the treating physician ordered some painkillers and anxiolytics. The following day, with the same symptoms, the patient went to the same health centre again, claiming that the pain was very severe, and on this second occasion, the diagnosis and treatment given were reiterated. After 8 days, the patient went to another health centre in a state of unconsciousness, where an examination revealed a sub-acute infarction in a cerebral artery, which resulted in a thrombosis that affected the mobility of one arm, the loss of vision in one eye and a neurological disability.

In this case, the judge constructed the *lex artis ad hoc based on* the principles applicable to the social security health system, which are found in article 3 of law 1438 of 2011. In addition, he referred to the Hippocratic oath, from which he deduced the obligation of professional due diligence and the application of the principles that make up medical ethics, concerning technical and ethical aspects. Finally, in the study of

the circumstances of time, manner, and place, the judge found that the first diagnosis should be considered a diligent act, since, according to the management guide for those symptoms, it was not possible to foresee or infer that the plaintiff's ailments would have the consequences.

It is important to make a reservation in this case, as Judge Ariel Salazar saved his vote to clarify that the *lex artis ad hoc* was not correctly delimited in the motivation of the judgement, provided that a more demanding level of diligence should be inferred from the guidelines for the management of the ailment. But not only that, and this is the interesting point of the question, the Magistrate affirmed that the indifference of the doctors to the pain and suffering of the patient disregarded the principle of benevolence that characterises the medical profession, so that the actions of the professionals should be considered negligent, provided that the pain of the patient was an alarm signal, from which the need for a more rigorous examination and diagnosis could be inferred. This is a postulate that, in the opinion of this writer, dignifies the position of the individual concerning health systems, but also incorporates ethical principles that must be respected by doctors, which not only obey the scientific nature of the profession, but also the humanity that it requires.

Concerning the same matter, the Third Section of the Council of State, in a judgment of 10 April 2019 (C. E., Third Section, No. 40916, 2019), studied a case in which the liability of a social entity of the State is analysed. The case consists of an obstetric injury, which occurred when a patient underwent a vaginal hysterectomy, but during the procedure, a perforation was caused in the rectum, which generated an infection that resulted in her death.

For the case, the court determined that the *lex artis* was the set of all the human, scientific and technical means available to doctors, considering the development of medical science at the time of the occurrence of the harmful events. Because of the above, it was concluded that the health institution acted negligently by making a hasty diagnosis that did not consider the necessary means to determine the existence of the infection. Thus, the treatment ordered for the postoperative period was insufficient to meet the patient's needs. Thus, the judge carried out a study of the *lex artis ad hoc* based solely on technical considerations.

In summary, considering all that has been explained, the *lex artis* is made up of two major elements: i) the technique applicable to the exercise of the medical profession, hence the so-called *lex artis ad hoc*, and ii) the rules that regulate the health sector and its professionals, whether these are ethical precepts, international conventions, laws, decrees or resolutions. However, this is a particular institution for cases of medical liability, which, it is worth clarifying, does not prevent a legal or technical vacuum from solving a specific case, since we cannot forget that the traditional legal concepts, such as professional negligence, good faith, the principle of trust, the position of guarantor (Jakobs, 1998) and others, are also applicable and of obligatory observance to determine medical malpractice.

Thus, up to this point, we have developed some particularities that characterise medical liability, this concerning the trial of liability, which applies to any of the possible jurisdictions competent to resolve this type of litigation in Colombia. However, it is important to clarify that these singularities are not sufficient to understand the civil and administrative experience on the matter, which is why, in the following, we will deal with each of these separately.

1.1. Medical liability

The first thing that is indispensable and necessary to point out is that medical civil liability arises on a contract. Nowadays, in the civil jurisdiction, it is not possible to study a case of medical liability under a non-contractual fact, which has a quite simple explanation and has to do with the compulsory application of the health benefit plans (PBS), which are covered by the insurers (EPS) and executed by the health care institutions (IPS), the vast majority of which are private. So, whether it is a contributory or subsidised scheme, it is sufficient for a private entity to provide a service covered by an insurer for a contractual relationship to be established between the doctor, the IPS, and the patient.

On the other hand, it is also possible to assess the liability of insurers, as these entities are responsible for authorising procedures, examinations, transfers, and medicines for patients who are covered by a voluntary or compulsory plan. Thus, a delay in the processing of a certain service may be attributable to contractual liability.

Now, the above does not prevent a person, outside the coverage of their insurer, from deciding to contact a doctor for a service, which is quite frequent in cases of cosmetic surgery (liposuction, rhinoplasty, bichectomy, blepharoplasty, among others) or dental treatment. However, the scenarios are covered by private contracts, which, as far as the resolution of conflicts is concerned, are heard before the civil jurisdiction.

However, one of the most important legal debates in the field of medical civil liability has to do with the type of contract that gives rise to these services (Hinestrosa, 2015, pp.

232-234)[3] , which is not a minor matter, since the negotiating figures allow the obligatory content of the parties to be deduced. Recalling, contracts have essential, natural, and accidental elements, where the first are those without which a certain type of negotiation would not arise, the second are those inherent to each contract and the last are those that the parties, under the negotiation, stipulate. Thus, the nature of the contracts makes it possible to determine the obligations to which each person, creditor or debtor, is bound, without the need to refer to the special provisions that the parties have agreed. In other words, each type of contract, *per se,* has a consubstantial content, which is understood to be agreed with the concretisation of private autonomy.

That said, the doctrine has mainly proposed two types of contracts for the provision of medical services: the mandate and the leasing of immaterial services. This will not be explained exhaustively, but the figure of the mandate was proposed to the extent that, in theory, the patient gives the doctor an assignment. However, if this were the case, the current legislation establishes that the principal has the possibility of issuing instructions to which the mandatary will "strictly adhere", which, to tell the truth, does not correspond to the reality of this service. This is provided that the doctor is the one who determines the treatment plan according to the conditions of the diagnosis; but it is also not true that, by this, the doctor has the possibility of acting "in the way that seems most convenient to him" (Civil Code, 2005, art. 2159), as is also indicated in the regulation of this type of contract (Jaramillo, 2019, pp. 203).

3 The contract, as a type of legal transaction, must be understood as a link arising from the agreement of wills of two or more persons, the purpose of which is the creation of an obligation or the creation, modification, or extinction of a legal relationship.

In addition, another criticism of the mandate contract states that the doctor does not have the possibility of acting on behalf of his client using representation, that is, a faculty that, although it does not belong to the nature of this type of business, is characteristic of it. In that order, the doctrine finds that the contract for the leasing of immaterial services is more appropriate for the provision of medical services, since it does not involve acting on behalf of or representing another, the main obligation of the debtor lies in the performance of a service in favour, solely, of the creditor (Jaramillo, 2019, pp. 204-209)[4] .

However, it has also been said that the leasing of immaterial services is not the right type of contract either, because it requires the intelligence of the service provider to predominate over the labour force, which is not at all suited to the activity of doctors, in which it is possible to use any of these resources for the performance of their work. Thus, it is not possible to affirm that all the rules of this type of contract can cover the entire relationship that exists between the doctor and his patient, which is why it has been proposed that the contractual link of medical services is atypical (Pizarro, 2014, pp. 827-830), a position that has been adopted by the Supreme Court of Justice (C. S. J., Civil Chamber, SC 5507-2001, 2001).

Consequently, the fact that there is no legal regime that makes it possible to design a contract for medical services, either as a mandate or a lease, obliges the doctrine to consider that these must be executed within the framework of an atypical scenario, which implies recognising the complexity of the medical dynamic if this is characterised by its changing *lex artis*

4 It cannot be overlooked that for some exceptional cases, the construction contract has also been proposed for medical services, this in cases of aesthetic surgical procedures.

and the dispersed applicable regulation. Indeed, the obligatory content of the medical contract requires interpretation in the light of the prevailing uses, practices, and knowledge for this profession (C. S. J., Civil Chamber, SC 5507-2001, 2001, p. 830), it is also necessary to bear in mind that, in some cases, consumer relations are configured (C. S. J., Civil Chamber, SC 2804-2019, 2019)[5] where the users of the health system deserve to be protected as weak parties to the contract (Giraldo, 2013, pp. 216-219).

Based on the above, the question then remains: What is the type of obligation that the professional contracts on the medical services contract? Much can be said about this since legal dogmatics has many criteria for classifying obligations (Hinestrosa, 2015)[6] , but about the contractual liability of the doctor, the discussion can be limited to the obligations of means and results.

The liability of a debtor is drastically altered when we speak of obligations of means or results. To explain the above, it is necessary to consider that obligations of means consist of the provision of service using all the standards of expertise, diligence, and prudence necessary for the achievement of an end, the latter understood as the main interest of the obligee. However, even though the latter goes into business with a specific objective, the fact that the obligor is only obliged to the performance of its possible means implies that the obligor cannot allege non-performance just because its interest has not

5 The jurisprudence of the Court has recognised the doctor-patient relationship as a consumer relationship, especially about the suitability of the service provided, without this implying the application of a strict liability regime.

6 Among the most common classifications are natural obligations, obligations to give, to do, not to do, of guarantee, means and results, security, joint, and several, conditional, optional, alternative, etc.

been realised. In this case, then, the obligor's liability is only possible when its actions do not correspond to the expertise, diligence, and prudence required for the provision of certain services (Hinestrosa, 2015, pp. 237-241).

In contrast, obligations of result imply for the obligor the achievement of an end, which must satisfy the interest of the obligee. This is the case, for example, of the obligations to give, where the effective delivery and tradition of an object are indispensable, a matter that in effect cannot be understood as the deployment of a set of judicious and well-intentioned actions that intend, but do not ensure, the achievement of an objective, but rather that it is necessary to achieve the result described in the negotiation agreement (Bonivento, 2017)[7] . Thus, in this type of obligations, the conduct of the obligor is not studied to qualify the non-performance, it is sufficient to establish whether the obligor complied with the promised result of the obligation, so that the expertise, diligence, and care are of no use when it is intended to exempt the obligor from liability (Bonivento, 2017).

Now, in contracts for medical services, professionals are not obliged to achieve a result it would be wrong for the doctor to ensure the cure of pathology when the truth is that this does not only depend on the capacities that he possesses. On the other hand, the regime applicable to the contractual liability of the doctor is determined by the obligations of means, according to which the doctor must use his skills and knowledge to achieve an end, which, in his field, is the prevention, diagnosis, and treatment of diseases.

7 The following contracts with performance obligations can be mentioned: purchase and sale, lease, work contract, mutual agreement, bailment, commodatum, exchange, deposit, etc.

In this order, and as the Supreme Court of Justice has understood, the performance of the doctor within a service contract is satisfied with the execution of his work carefully and diligently, but in addition to this, it is also necessary to take into account the application of the *lex artis*, this being understood, I repeat, as the body of knowledge that medical science has for a given time and case (C. S. J., Civil Chamber, SC 7110-2017, 2017).

This issue of obligations of means in medical service contracts has been so widely accepted that Article 104 of Law 1438 (2011) states that the relationship of "health care generates an obligation of means". So, the problem remains to determine in which events the physician's obligation is one of the results. For this, the solution is quite simple and following the position of the Court (C. S. J., Civil Chamber, SC 7110-2017, 2017), we can affirm that the health professional will be obliged to the achievement of a result when so stipulated in the contract (M'Causland, 2019, p. 583), which can be seen in some cases of aesthetic surgeries.

Additionally, in a recent judgment of 7 December 2020 (C. S. J., Civil Chamber, SC 4786-2020, 2020), citing a judgment of 5 November 2013 (C. S. J., Civil Chamber, SC 2005-00025, 2013), the Court (2013) indicated that the obligations of results could also be configured in those cases in which "the margin of uncertainty of the medical activity is reduced because the variables that can negatively influence recovery are under the control of the professionals" (s. p.). *In* that order, when medical treatment or procedure has the possibility of directly influencing a person's health, with such a level of assertiveness that recovery can be assured, the health professional's obligation will no longer be one of means but one of the results. This is

also the case for damages arising from the omission or delay in the provision of medicine, examination, laboratory analysis, immobilisation of a limb, or fitting of an orthopaedic appliance.

Thus, the general rule is that the obligation contracted by the doctor is one of means, as established by regulation and jurisprudence, in which case diligence and care, based on the *lex artis*, serve to exempt him from liability. Exceptionally, however, the obligations will be of result, in which case the exemption from liability is only found in the effective fulfilment of what was promised or the existence of force majeure.

Having said the above, up to this point, we have evacuated those particularities that characterise the medical civil liability trial in Colombia, which can easily coincide with the experience of other latitudes. Now, after the trial, the most important aspect of liability is the evidentiary regime, after all, it is through this that each of the categories that give rise to the indemnity obligation is fed. Thus, it is important to determine the allocation of the burden of proof, in other words, who, how, and why must prove. This is, in short, a matter of the first order for any judicious jurist.

As far as the evidentiary regime in medical liability is concerned, the most important developments have been in the category of fault, which is hardly consistent with what has been explained up to this point, since the general rule is that the physician's obligation is one of means, which requires qualifying his conduct to determine whether he has incurred non-compliance and, therefore, liability.

To begin with, one of the main theories on the allocation of the burden of proof in these cases is found in Article 1604 of the Civil Code (2005), which recites that "proof of diligence or

care is incumbent on the one who should have used it; proof of an act of God is incumbent on the one who alleges it". By this provision, it is said that the physician, as the party obliged to exercise diligence and care, is the contractual party responsible for proving the absence of fault, which in practice has the effect of a presumption in favour of the patient. Consequently, if the latter proves, within the trial, the existence of an injury and its causal relationship with the health care service, the presumption operates, which results in a condemnatory sentence, when the doctor does not demonstrate that his actions correspond to the *lex artis*.

In the previous position, there are doctrinaires, such as Professor *Fernando Hinestrosa*, who indicate that they agree. However, the way to reach this conclusion is different, since, according to article 1757 of the Civil Code, every creditor must prove the obligation that it intends to enforce and its breach, so it would be understood that the general regime applicable to the obligations of means is one of proven and not presumed fault. But in the case of health care contracts, given the ease with which the doctor has access to the means of conviction, he or she is the one called upon to bear the burden of proof, so it would be worth applying the presumption of fault (Hinestrosa, 2015, p. 586).

On the other hand, and considering the rules of the mandate contract, let us remember that this type has been proposed for medical services, it has been said that under the last paragraph of article 2184 of the Civil Code, the principal will be responsible for proving the agent's fault, which means that the patient must prove that the doctor has been negligent (Tamayo, 2015, p. 1090).

From what has been mentioned so far, it is important to bear in mind that within the legal world it is considered that a presumption of fault is a prerogative that facilitates the plaintiff's action within the process and that the opposite is a neutral or impartial scenario, but the truth is that a proven fault regime is nothing other than a presumption of diligence in favour of the defendant (M'Causland, 2019, pp. 579-652). However, in this writer's opinion, one or the other of the above-mentioned presumptions is a matter of argumentative order that reaches into legal policy. The position adopted by the Court, as far as medical contracts are concerned, is a proven fault regime (C. S. J., Civil Chamber, SC 2804-2019, 2019), which is based on the protection of medical activity as a socially useful profession, a matter that will be discussed in the following sections.

Despite the above, it cannot be left aside that, currently, for any kind of process there is the theory of the dynamic burden of proof, which came about with the implementation of Article 167 of the General Code of Procedure. This rule determines that the judge, at the request of any of the parties or ex officio, may order the reversal of the burden of proof, a matter that only depends on the conditions of the specific case, where it will be analysed who is in the best position to provide the means of conviction. Thus, if the doctor is in a better position to prove, the patient may request a reversal of the burden of proof concerning one or more of the facts that are not established in the litigation. This is a tool that is not only applicable to a fault but to any of the elements of the trial.

In summary, in this section, we address the experience of medical civil liability in Colombia, for which we explain the contractual typology, the type of obligation contracted by the health professional, and the evidentiary regime applicable to

these cases, as the most important points for this matter. We will then go on to explain the medical liability of the State in Administrative Law.

1.2. Medical liability of the State

In comparison with civil liability, the liability of the state brings to the academic and judicial world more demanding debates that deserve a high argumentative content, not only because one of the subjects involved in the litigation is the Colombian state, but also because of the absence of norms in this respect, a matter that does not allow controversies to be avoided with the reasoning of syllogism and interpretation[8] . In effect, the non-contractual liability of the state is based solely on Article 90 of the Political Constitution, a norm that has served for the development of all the categories of the trial.

Thus, the medical liability of the State develops in a different dynamic to that of civil law, so much so that all cases are analysed in the extra-contractual scenario, in addition to the fact that the health care service must be provided by a State Social Enterprise (ESE), which may be a public Health Care Provider Institution (IPS), that is, a hospital or a Health Services Provider Unit (UPSS).

To explain why the medical liability of the State always occurs in the non-contractual sphere, it is necessary to understand that in Colombia health care is part of the State's provision of services, which is a service that must be guaranteed according to the infrastructure and budget possibilities of the public administration. This is following Article 49 of the

8 Exceptionally, within the liability of the State, there are some cases with their own rules, as is the case, in the non-contractual sphere, of liability for judicial error, defective functioning of the administration of justice, and unjustified deprivation of liberty. In turn, in the contractual sphere, all the rules regulate all the types of contracts that the state can and must enter into.

Political Constitution (1991), which states that "Health care and environmental sanitation are public services provided by the State. All persons are guaranteed access to health promotion, protection, and recovery services".

Moreover, when an ESE or UPSS provides a health service to a person, it does not do so by a contractual relationship, but through a regulated activity of a welfare nature guaranteed by the State. Consequently, the patient is understood as a user of the health system, who does not previously have a business relationship with the service provider (C. E., Third Section, No. 36738, 2017). Now, it has long been known that non-contractual liability arises in the context of occasional events, which are characterised by being eventual or contingent, but in these cases, the situation is quite different, since the provision of health services by the State is framed within the scope of public policies, which are governed by the principles of legality and administrative planning.

Now, the trial of non-contractual liability of the State is constituted with the same three presuppositions of civil liability, namely: damage, imputation, and basis or attribution factor. However, it is pertinent to clarify that the legal nomenclatures change. In other words, the essence of State liability has the same logic as civil liability, i.e., the emergence of a compensatory obligation based on the three assumptions: damage, imputation, and grounds, but within these three categories there are different terminologies which, briefly, we will explain below.

There is not much to say about damage, because the differences only lie in the issue of the typologies of non-pecuniary damage, which is not relevant to what we are going to deal with, so I recommend its study in a separate text.

As far as imputation is concerned, the matter is a little more complex. Let us remember that it can be factual or normative, where the former is the causal relationship that exists between the agent's conduct and the damage suffered by the victim, and the latter consists of attributing damage based on legal duty. In civil matters, the normative imputation can occur, for example, in the regime of liability for the acts of others, in these cases the liable party has not deployed any action, but under a legal duty, the damage is attributable to him. The same is true for cases of the act of things, where guardianship can be a criterion of imputation. However, the figures are proper to civil law they are enshrined in the code.

However, the above does not operate in the same way in the administrative jurisdiction, since the advent of normative imputation occurred on the theory of objective imputation in criminal law (C. E., Third Section, No. 21928, 2012). Thus, the legal duties for the attribution of damage no longer rest on criteria such as the actions of others or the protection of things but are developed based on the permitted risk, the principle of trust, the position of the guarantor, the action at one's own risk, the prohibition of return and the purpose of protection of the norm, all these tools with criteria and conditions of jurisprudential construction (Gil, 2015, pp 75-130).

Concerning the bases or attribution factors, there are three in the liability of the State, the failure of service, exceptional risk, and special damage, the first two brought from the general theory of liability and the last one a figure specific to Administrative Law (Rodríguez, 2017, pp. 321-332). Let us see, failure in service is nothing other than the fault, but its connotation responds to the disregard of the legal obligations required by the exercise of the administrative function. Let

us remember that the actions of the authorities are regulated and subject to the principle of legality, so that the failure is not evidenced by the existence of an open archetype, such as the good father of a family, but is seen in the light of the principles and laws that determine how the public administration should act. In that order, the failure can be due to the non-provision of public service, defective provision of the same, or late provision (C. E., Third Section, No. 4910, 1986; C. E., Third Section, No. 53953, 2020).

On the other hand, the exceptional risk is a basis that comes from the objective theory of liability, where the lawful increase of the normal levels of risk allows the attribution of damage without qualifying the conduct of the State so that the applicability of the compensation obligation only depends on the proof of the damage and the factual or normative imputation. Thus, the construction of work or the provision of a service using instruments or activities that place individuals in a situation of exceptional risk is susceptible to liability under an objective regime (C. E., Third Section, No. 4655, 1989; C. E., Third Section, No. 49426, 2020).

As far as special damage is concerned, this is a specific type of state liability and, like the exceptional risk, it occurs in the context of lawful action. Now, in this case, the basis is the principle of equality before public burdens, which aims to maintain the demands of the state equitably among its citizens, so that no one must bear a particular imposition. Consequently, when the state imposes an exceptional burden on a citizen through a lawful act, the latter has the possibility of claiming compensation for the damage suffered. An example of this occurs when a private individual is subjected to a security measure in criminal proceedings and then acquitted, without

the judge or the prosecutor's office has failed to act. In this case, the lawful action of the administration results in special damage that does not correspond to the public burdens that every citizen must tolerate (C. E., Third Section, No. 1482, 1976; C. E., Third Section, No. 55901, 2020).

Having said the above, within administrative law, the general liability regime applicable to health care services is subjective, i.e., through the basis of service failure. In turn, but exceptionally, strict liability is also applicable, based on the exceptional risk factor.

Regarding subjective medical liability, we should mention that, as in the civil jurisdiction, the main debate has arisen around the category of failure of service. However, the discussion is not about what is understood as negligence or not in these events, for which the traditional methodology of the Council of State has not changed, but about the applicable evidentiary regime. The above, is worth noting, with a particularity: let us remember that in civil matters some normative provisions allow us to conclude the allocation of the burden of proof, but in the case of the non-contractual liability of the State this is not the case.

For this reason, at first, the medical liability of the State developed in a regime of proven failure, which assigned the burden of proof to whoever sought to enforce the effect of a rule, so that, if a private individual requested the liability of the State, the latter had to prove the existence of damage, imputation, and failure of service. In contrast, as it was in its interest, the state had to prove the grounds for exclusion of liability (Gil, 2015, p. 636).

After this, the Council of State, through its jurisprudence, determined that the evidentiary regime applicable to medical liability consisted of presumed failure if the administration has to demonstrate that it acted diligently, insofar as its activities are governed by the principle of legality. Thus, it was only necessary for the individual to prove the damage and the imputation, and it was the State's duty to prove the non-existence of failure or any of the grounds for exclusion of liability (C. E, Third Section, No. 5902 1990).

In addition, the presumed failure regime also rested on the idea that the administration, in these cases, as the provider of health care services, is in a better position to prove, since its knowledge of medical science allows it to access the means of conviction in a simpler way (C. E., Third Section, No. 6897, 1992).

However, the position was debated by the Council of State itself, since it was said that the theory of presumed fault assumed that in all cases one of the parties was in a better position to prove, a matter that could not be applied as a rule because it lacked empirical verification. Thus, it was concluded that the most accurate way to determine who was in a better position to prove was through a dynamic theory, which is based on the principle of fairness for the allocation of the burden of proof so that this depends on the study of each case (C. E., Third Section, No. 11878, 2000).

Now, the main criticism that the dynamic theory of evidence received is that advisors and judges did not have the legal power to modify the burden of proof within the process, a point that was avoided with the issuance of the General Code of Procedure and its figure of the dynamic burden of proof, which is applicable in administrative proceedings under article

211 of the Code of Administrative Procedure and Contentious Administrative Proceedings.

On the other hand, regarding objective medical liability, this is a regime that has been developed in an exceptional manner, which only proceeds in certain cases, which are enshrined in case law. Thus, according to the Council of State, the health care service gives rise to the objective regime in the cases of intrahospital or nosocomial infections, application of vaccines, supply of medicines, and when new therapeutic methods with unknown consequences are used (C.E., Third Section, No. 20878, 2011; C. E., Third Section, No. 21515, 2012; C. E., Third Section, No. 22424, 2012). In the following, we will explain each of these scenarios.

1.2.1. Nosocomial infections

Concerning the first scenario, nosocomial infections, it is necessary to explain that these are those acquired during the performance of in-hospital medical treatment, which may occur in the performance of surgery, when a patient is treated in the emergency room or when he/she requires hospitalisation and observation in intermediate or intensive care. However, the particularity of this type of infection is that they do not arise from the pathology for which the user comes to the health care service but is transmitted during the provision of the service. An example of this was a case study by the Third Section of the Council of State, in which a pregnant woman was admitted to a hospital to give birth, however, after the procedure, the patient presented symptoms of an infection acquired during childbirth, which caused a multisystemic organ failure and, therefore, death (C. E., Third Section, No. 26124, 2012).

It is worth saying that there are two positions on this point, the first of which posits that nosocomial infections are a risk inherent to the medical activity of healthcare systems so that informed consent makes it possible to transfer the realisation of the risk to the patient's responsibility. This is the theory held by the Civil Chamber of the Supreme Court (C. S. J., Civil Chamber, SC 2202-2019, 2019). Thus, liability for this type of disease is only possible when it is proven that the IPS or the doctor acted negligently in the implementation of the epidemiological protocols, the latter understood as the technical guidelines aimed at eliminating, controlling, or mitigating the effects of infectious diseases.

In contrast, the Third Section of the Council of State has determined that nosocomial infections imply a risk that must be borne by the state and that informed consent does not allow this to be transferred to the patient. This is if there are reasons for distributive justice and equity through which the public entities providing health services are called upon to assume the damages that occur on an intra-hospital infection. It has also been mentioned that in these cases consent cannot be considered perfect, since it is impossible to inform the user about the totality of the possible infections that he or she may contract and their consequences, which is indispensable when it is intended to transfer the risks of the medical act to the patient (C. E., Third Section, No. 396122, 2017).

Thus, the liability regime applicable to nosocomial infections is objective, which is based on the title of exceptional risk[9], making it impossible for public entities to exempt

9 Despite the above, a question arises based on the context in which these lines are written. Will the damages caused by COVID 19 nosocomial infections be attributable to the state based on the strict liability regime? Concerning this question, we will only make a small comment. Let us recall that in the strict liability regime due diligence and fortuitous event

their liability by proving due diligence in the application of epidemiological protocols, as could be done in a subjective regime - as is the case in the liability regime of the Civil Chamber of the Supreme Court of Justice (C. S. J., Civil Chamber, SC 2202-2019, 2019).

1.2.2. Application of vaccines

Within public health policies, most countries have implemented immunisation programmes for the population against certain infectious diseases, for which vaccination plans have been essential. Today, the vaccination schedule in Colombia is oriented toward all children under 6 years of age, which has around 22 vaccines for 26 types of diseases. It is also important to note that there are plans for adult immunisation, but with lower coverage and only for 7 diseases (Ministry of Health and Social Protection, 2020).

However, even though the objective of vaccination is to immunise people against certain diseases, the application of these medicines can, in some cases, have negative side effects on people's health. For this, the Third Section of the Council of State has determined that the applicable liability regime is objective, this based on the title of exceptional risk, since a lawful act of the State in the implementation of this type of public policy has the effect of an unusual alteration of the risk for certain people, who should not bear the negative effects of health programmes (C. E., Third Section, No. 41390, 2019).

are not exemptions from liability, but force majeure and the act of a third party are. Thus, it will be of vital importance to determine to what extent the conditions of the Colombian Health System may constitute a force majeure scenario, where high levels of care and scarce resources are fundamental to determine whether or not the State could have acted otherwise. At the same time, it should be considered whether informed consent, concerning COVID 19, could be a tool for risk transfer, as patients were aware of the risks and consequences of attending the health system in times of pandemic.

By way of example, we can mention a case in which the responsibility of the State for the application of a polio vaccine was studied. The facts were that a mother took her two-and-a-half-month-old daughter to a health centre for the application of the vaccine, which happened normally, but days later the child presented health complications and, in a new visit to the health service, she was diagnosed with a post-vaccination polio infection, a pathology that caused her permanent quadriplegia (C. E., Third Section, No. 41390, 2019).

The reason for establishing strict liability in these cases is that the State, in its immunisation schemes and plans, implicitly assumes the possible danger and adverse reactions of vaccines in different types of organisms. Thus, due care in the transport, conservation, cold chain, and application of vaccines does not serve to exempt itself from liability as an act of diligence, nor does the fortuitous event, understood as the unpredictability of the effects of these medicines. Thus, the objective regime in these cases will only allow force majeure and the act of a third party to serve as exonerating factors in the liability trial (Cely, 2020).

1.2.3. Supply of medicines

There is no need to comment on this case this case works the same as the one explained in the application of vaccines (C. E., Third Section, No. 40562, 2017). Vaccines are medicines, and this regime is foreseen for cases in which damage can be caused by the supply of analgesics, anxiolytics, antipyretics, anti-inflammatory, anti-gout, anti-allergic, anticonvulsants, antibiotics, antibacterials, anticoagulants, antihypertensives, antirheumatics, antacids, diuretics, disinfectants, among others (World Health Organisation, 2007).

However, it is important to bear in mind that when we talk about the supply of medicines under the strict liability regime, we are only referring to the unforeseeable side effects that these can generate in different organisms. Liability for the failure to supply medicines or a mistake in prescribing them are assumptions that must be studied under the title of failure of service within the subjective regime (C. E., Third Section, No. 35116, 2016; C. E., Third Section, No. 36933, 2016).

1.2.4. New therapeutic methods with unknown consequences

Finally, the strict liability of the state for the application of therapeutic methods with unknown consequences is based on the execution of the medical activity in a risky manner, with the aggravating factor that the possible effects of a certain treatment are not known, which does not allow the patient to give informed consent, as this should consist of an explanation of the procedure to be carried out with its possible benefits and negative effects (C. E., Third Section, No. 17733, 2009). Thus, the basis used in these cases is the exceptional risk, however, it is important to mention that the jurisprudence on this point is quite scarce.

With the above, we conclude the section on state medical liability. In the following, we will make some brief reflections on what has been explained in civil and state medical liability, considering the particularities of each of these regimes.

2. SOME REFLECTIONS ON CIVIL AND STATE MEDICAL LIABILITY: A CRITIQUE OF THE IRRELEVANCE OF INFORMED CONSENT IN THE LIABILITY SUIT

Up to this point we have dealt with many issues, this journal article began by analysing, in a comparative manner,

the civil and administrative experience of medical liability, considering the doctrine and jurisprudence of the Civil Chamber of the Supreme Court of Justice and the Third Section of the Council of State. However, I cannot leave these lines without first making a quite specific criticism of what has to do with medical liability and informed consent.

First, the first thing I should point out is that my criticism consists of the irrelevance of informed consent in the liability trial, given that, in jurisprudence - especially in civil experience - no practical application of this figure can be found. In other words, judges do not attribute any effect to the disregard of informed consent by health professionals, even though academia and jurisprudence consider that this figure acts as a prerogative of self-determination in favour of the patient, which is linked to the fundamental rights of freedom and the free development of personality. At the end of the day, informed consent is the tool that allows the patient not to be a means of medical practice, but an end, which serves to recognise the subjects as free persons capable of deciding on their health and personal integrity.

Thus, the structure of this section will be developed as follows: first, the figure of informed consent and its importance for the practice of medicine will be explained, followed by the experience of the Supreme Court of Justice and the Council of State, and finally, we will explain the error made by the jurisprudence in not granting effects to the lack of informed consent in the trial of liability.

2.1. Informed consent and its relevance to the practice of medicine

Informed consent is the part of the medical act in which the health professional informs the patient about the procedure to be performed so that the patient can give or withhold his or her consent. So, while it is true that the professional is the one who knows the medical science, it is only the patient who can decide about his or her health and personal integrity, this is what is known as self-determination.

Now, to inform the patient about the applicable medical procedure, it is not only required that the professional specifies what it consists of, but it is also necessary to fully, clearly, and sufficiently explain the possible risks and benefits of the therapeutic or surgical treatment that will be carried out, also considering the material or logistical shortcomings of the IPS, when applicable. The problematic nature of this issue is such that it is practically related to all medical acts since if there is no clear communication between the professional and the patient, it can generate a wrong consent or, for example, suppose that the doctor makes a mistake in the diagnosis and informs about a treatment that is not suitable, in this case, the patient will issue an authorisation that does not correspond to the reality of his/her health condition (García, 2018, p. 125).

Indeed, informed consent is a vitally important issue, provided that the patient has a right to be informed and to decide about his or her body and personal integrity. Indeed, the Lisbon Declaration on the Rights of the Patient, adopted by the World Medical Assembly, states in paragraph 3, subparagraph "a" that: "The patient has the right to self-determination and to make decisions freely concerning himself/herself. The physician shall inform the patient of the consequences of his or her decision".

Additionally, paragraph "b" of the same numeral, it mentions that: "The mentally competent adult patient has the right to give or withhold consent to any examination, diagnosis or therapy. The patient has the right to the information necessary to make his or her decisions" (World Medical Assembly, 1981).

In turn, the Oviedo Convention recognises consent as a Human Right, in the following terms: "An intervention in the field of health may only be carried out after the person concerned has given his or her free and informed consent" (Council of Europe, 1999).

As far as the Colombian legal system is concerned, informed consent is not recognised as a right of the patient, but as a duty of the physician, who must request it for any kind of procedure. This is found in Article 15 of Law 23 (1981), which states that:

> The physician shall not expose his or her patient to unjustified risks. He shall seek the patient's consent to medical and surgical treatment that he considers necessary, and which may affect him physically or psychologically, except in cases where this is not possible, and shall explain the consequences of such treatment to the patient or those responsible for him in advance. (art. 15)

However, Article 8 of the law indicates that the patient is free to dispense with the services of the physician. However, it is important to clarify that in cases of urgency, informed consent is dispensable for the practice of a medical act, such as when a person suffers an accident, becomes unconscious, and requires medical attention, in these emergency cases the duty of care allows the physician to act without informing the patient or his relatives.

On this point, in a judgement of 12 September 1994 (C. C., T 401/94, 1994), the Constitutional Court has indicated that informed consent is a fundamental tool for the exercise of the right of every patient to refuse the application of the treatment on his or her body. In addition, it was mentioned that, in the medical relationship, both the patient and the professional have the possibility of withdrawing and, if this is not done, the doctor must inform the patient of all the implications of the treatment. Finally, the Court recalls that there are three cases, for reasons of vital urgency, where consent is not necessary: i) when the patient's mental state is not normal, ii) when the patient is in a state of unconsciousness, and iii) when the patient is a minor.

Despite the above, it is important to point out that all the above-mentioned provisions, both at the international and national level, have not been sufficient to ensure that in all cases health professionals fully respect the right of patients to be informed and, on that basis, to give or withhold consent. At this point, it is essential to mention a very common case, which has to do with the practice of obstetrics and gynaecology, where violent practices by medical personnel are recurrent, including the lack of information to women about the different procedures performed during childbirth, which have negative consequences on sexual and reproductive life (Pozzio, 2016, p. 101-106). Such as an example, the carrying out of unnecessary cessations (DANE, 2018)[10] , repetitive vaginal examinations without justification, frequent use of oxytocin to accelerate labour, and, the most serious of all, the practice of episiotomy

10 The performance of unnecessary caesarean sections is one of the most recurrent violent practices, especially when the health professional has not obtained consent for it. The World Health Organisation has indicated that C-sections should not exceed 15% of births, but in Colombia, this figure is as high as 45%.

without consent, which consists of a vaginal incision to widen the exit canal of the foetus (Barbosa and Modena, 2018, p. 2).

In summary, informed consent is, more than a duty of the physician, a fundamental right of the patient to be informed and to give or withhold consent to the procedure proposed by the physician, which must be explained clearly and considering its risks and benefits, with the aim that the patient's decision is free of force or error.

2.2. Jurisprudence of the Supreme Court of Justice and the Council of State: the irrelevance of informed consent

Having said this, we will mention some of the jurisprudential references that have been made to the issue of informed consent, from the perspective of the Supreme Court of Justice and the Council of State. Thus, we will look at each of these points in separate items.

2.2.1. Civil Chamber of the Supreme Court of Justice

The first case decided on 26 July 2019, arises from the practice of "refractive surgery with laser excision to correct high myopia and reduce dependence on contact lenses and glasses" (C. S. J., Civil Chamber, SC 2804-2019, 2019, s. p.), this procedure was performed on each of the patient's eyes two days apart.

However, the result of the surgery was not the desired one and the patient lost a percentage of her vision, which, according to the defendant's doctor, was an inherent risk of the procedure. Now, one of the main arguments of the plaintiff to prove medical negligence was the lack of information necessary to issue consent. It was proven in the process that the professional had not informed the patient adequately so the patient was not fully aware of all the risks involved in the practice of the procedure.

Despite the above, the judgement states that the lack of informed consent has nothing to do with the act of negligence that must be proven for an obligation to pay compensation to arise. Thus, the defendant's doctor proved in the proceedings that he had carried out all the necessary procedures for the proper performance of the surgery so that in no way could fault be asserted as a basis for the liability judgement. In summary, the court mentioned that the claimed damages were not an unavoidable consequence of the doctor's failure to comply with his duty to inform. Consequently, the doctor was acquitted.

On the other hand, in a ruling of 14 December 2018 (C. S. J., Civil Chamber, SC 5641-2018, 2018), a patient underwent a surgical procedure to have material removed that served her to recover from an "anterior cervical arthrodesis". However, once she came out of the operation, the patient was in severe pain, for which the anesthesiologist ordered an analgesic and then proceeded to evaluate her, finding an oximetry problem, for which reason a transfer for intubation was ordered. Once in intensive care, the doctors noticed sudden oedema in the back of the neck, and an attempt was made to remove the haematoma by performing surgery, but while the procedure was being carried out, the patient died, so the postoperative period for the main surgery lasted no more than 80 minutes.

According to the evidence in the case, it was determined that the doctors had not acted negligently, as what happened was an inherent risk of the surgery. However, when the informed consent was reviewed, it was found that there were several inconsistencies in the information that the doctors provided to the patient before the surgery. But as in the case, the judge did not consider that such omission was susceptible to breach of contract, so the defendant clinic was acquitted (C. S. J., Civil Chamber, SC 5641-2018, 2018).

Finally, in a judgment of 24 May 2017 (C. S. J., Civil Chamber, SC 7110-2017, 2017), a patient required the practice of a "laparoscopic cholecystectomy", that is, a surgery through which the gall bladder is removed. However, in the post-operative period, the patient had abdominal pain that forced the professionals to perform some additional tests, where it was discovered that the first procedure performed had perforated the small intestine, which generated a rather dangerous infection.

In this case, again, the court found that the patient had not been adequately informed about the risks of the procedure. However, following the logic explained above, it was concluded that the lack of consent had no bearing on the medical practice so the risk was inherent to the procedure performed. Furthermore, bordering on rudeness, the ruling mentioned that the defendant's professional was "connoted" so that his capacity allowed him to expertly perform the laparoscopy, which left aside the fact that he had not provided the necessary information for the patient to decide about her health and personal integrity. In other words, according to the Court's reasoning, the more reputable the doctor's reputation, the lesser the duty of information he has towards his patients (C. S. J., Civil Chamber, SC 7110-2017, 2017). Thus, the defendant's liability is not proven.

Despite the above, in a recent judgment of 7 December 2020 (C. S. J., Civil Chamber, SC 4786-2020, 2020), the Court analysed a case in which a woman underwent cosmetic surgery for liposuction. However, after the intervention, the patient suffered abdominal pain, pallor, and other abnormal conditions that caused multi-systemic damage to her health and led to her death. In this case, the plaintiff argued that the victim's death was the result of medical negligence.

Thus, the particularity of this case lies in the fact that the court found the means of proof to ensure that the defendant's doctor had undertaken to perform an obligation to achieve a result. Not only that but in the *obiter dicta of* the judgment, it is stated that a correct disclosure of the risks and the respective consent of the patient to these risks mitigates the doctor's liability, even though the doctor has committed himself to the achievement of a result. In addition, and coming to the most important point, the Court affirmed, for the first time, that in the absence of informed consent, medical personnel must assume the consequences of their omission and diligence cannot exempt them from liability (C. S. J., Civil Chamber, SC 4786-2020, 2020).

Several doubts arise from the above, since in this case the argumentation was not used in the *ratio decidendi* of the ruling, provided that in the specific situation force majeure operated as an exonerating factor for liability. Then, the question remains as to how the absence of informed consent would operate in the liability trial, what are the consequences the medical personnel would bear, is it possible to state that the absence of informed consent is a necessary cause of the damage, and does the absence of informed consent constitute a relative nullity due to error in the medical services contract, and if so, what are the consequences?

As can be seen, although the judgment brings up the issue of informed consent and gives it special relevance, given that no attempt had ever been made to incorporate this concept within the liability trial, on this occasion, it does not make much progress in this respect either, or the matter remains a mere doctrinal reference.

Considering the above, in the jurisprudence of the Supreme Court of Justice it is irrelevant, within the liability trial, whether the doctor provided the necessary information for the patient to issue the respective consent, since, under the logic, this has no direct impact on the practice, i.e., whether the doctor was diligent and, therefore, acted with negligence. However, the last judgment analysed the possibility of liability based on the lack of informed consent but did not specify how this could be done; this reference was only a doctrinal citation (C. S. J., Civil Chamber, SC 4786-2020, 2020).

2.2.2. Third Section of the Council of State

Now, the dynamics of the jurisprudence of the Council of State, as far as the assessment of informed consent is concerned, have developed similarly. To explain this issue, we will look at some cases that will be explained below.

On 3 April 2020 (C. E., Third Section, No. 43034, 2020), the Council of State studied a case in which a minor, accompanied by his parents, went to the health service of a hospital for a congenital cataract, for which the treating ophthalmologist diagnosed that surgical intervention was necessary. Indeed, the ordered procedure was carried out correctly and following the urgency that the patient's situation required. However, days later, the child returned to the hospital with an infection that, traditionally, could have been acquired due to a lack of surgical asepsis and instruments in the post-operative period. At that time, the procedure should have been performed urgently, but a delay on the part of the medical staff resulted in the child's loss of vision. Furthermore, the hospital had the burden of proof to demonstrate the correct application of the procedures established in the protocols that mitigate infectious diseases and timely care.

However, the defendant failed to prove that the protocols had been applied, that the delay of the medical staff had not caused the damage and, additionally, there was no evidence of the informed consent of the child's parents throughout the proceedings. Regarding the latter, the judge considered that this act was reproachable, but did not give it any effect other than considering it a negligent act among the many others committed by the hospital (C. E., Third Section, No. 43034, 2020). Thus, the lack of sterilisation measures and the delay in care were the facts that constituted the evidence of service failure for which the State was condemned.

In a judgment of 11 March 2019 (C. E., Third Section, No. 46283, 2019), a case was decided in which a woman went to the health service of a hospital because she presented a mass in her neck; consequently, the treatment physician diagnosed a "thyroid goitre" and the need for a surgical procedure to reduce the thyroid gland. After the procedure, the patient noticed a loss of vocal ability, and, after consulting other professionals, it was determined that the surgery had resulted in irreversible damage to her vocal cords.

One of the claimant's arguments was that the informed consent had not been given correctly, however, the evidence found that the patient had signed a document stating the risks of the surgery, as well as, in the interrogation, she claimed to have been informed about the surgery.

Thus, the judge, citing a ruling of 3 July 2007 (C. E., Third Section, No. 16098, 2007), indicated that the informed consent acted as evidence that served as an exoneration of liability, since, if the damage was the realisation of one of the risks informed to the patient, the defendant entity should not bear the damage suffered by the plaintiff, since the provision

of information allows the risk of the medical activity to be transferred to the patient. Accordingly, the state absolves the state of liability (C. E., Third Section, No. 16098, 2007).

In a judgment of 26 October 2018 (C. E., Third Section, No. 41144, 2018), the case of a man who went to the health service with symptoms of respiratory distress was studied. After some tests, the medical staff diagnosed gall bladder stones and biliary inflammation, for which, in principle, hospitalisation in intermediate care was ordered and then he was discharged. After a few days, the patient had to return to the health service twice due to gall bladder inflammation. On a final occasion, the patient attended the emergency department where he underwent unnecessary surgery to remove his gall bladder, without his consent, which resulted in harm to his integrity.

In that order, the judge analysed informed consent as a tool to determine whether an exemption from liability was applicable (C. E., Third Section, No. 41144, 2018), however, as mentioned, there was no evidence of consent for the surgery in the file so that the State was condemned for the realisation of a risk that it did not transfer with the patient's authorisation. Apart from this, the absence of informed consent had no other effect.

Thus, in the jurisprudence of the Council of State, informed consent is used to determine whether the defendant has acted diligently, intending to disprove the basis of service failure. Thus, when it becomes evident that the doctors have not provided the information on the procedures to be performed or have done so, but inadequately, this only results in the impossibility of using consent as an exoneration of liability, but not as evidence that can autonomously determine negligence.

3. INFORMED CONSENT AS AN ESSENTIAL ELEMENT IN DEFINING THE APPLICABLE LIABILITY REGIME

Up to this point, after all the analysis carried out on informed consent, it is barely evident that there is a logical contradiction between what is established in international and national provisions on patient autonomy and the recognition that the high courts, in liability proceedings, attribute to this figure. As can be seen in the previous lines, in civil jurisprudence it is irrelevant, within the liability trial, whether the doctor obtained the patient's consent. This is a similar issue in administrative matters, where it only functions as a means of proof to exempt the State from liability.

In my opinion, the irrelevance of informed consent in the liability trial is a matter that violates the fundamental and legal rights of the victims, which should affect the analysis of the arising of the indemnification obligation, whether it is a matter of contractual liability, for the civil case, or non-contractual liability, for the administrative case. Thus, the legal arguments on which this criticism is based will be developed here.

To explain this, I will give the following example:

A pregnant woman presents with symptoms of labour, which is why she decides to go to the medical service of an IPS for treatment. Coincidentally, however, the patient arrives at the emergency department when the obstetrician-gynaecologist in charge, who is quite reputed in his profession and has written several scientific articles on the practice of caesarean section as an acceptable and suitable procedure for childbirth, is about to finish his shift.

However, once the mother is admitted to the emergency department and is ready to be attended to for a

vaginal delivery, which can last between 6 or 10 hours, the doctor orders a caesarean section, a surgical procedure that takes approximately 1 hour. Now, all the above was carried out without informing the patient in a clear, complete, and sufficient manner about the reason for this procedure, its risks, and benefits.

One day after the surgery, due to symptomatology of infection, the medical staff noticed a lesion in the patient's intestines caused by the procedure, which is a risk inherent to this type of surgery, and ignored the doctor's carelessness.

Once the patient has recovered from the surgery and after the days of incapacity caused by the injury, she decides to consult her lawyer about the procedure that was performed, for which he verifies the medical history and finds no evidence of informed consent about the caesarean section, indicating that the treating physician and the IPS violated her right to be informed about the risks and benefits of the procedure. Considering the above, the lawyer recommends filing a liability suit for the damages caused by the uninformed surgical procedure.

Well, in the light of the majority case law of the Supreme Court of Justice, this case would not give rise to an obligation to pay compensation, since the procedure that caused the damage was performed by an expert and in compliance with the *lex artis*, so that it is impossible to prove the doctor's fault, since, as the Court has mentioned, the lack of informed consent is not sufficient to prove a breach. On the other hand, considering the jurisprudence of the Council of State, in this scenario compensation would not be possible either, as the consent would only serve to demonstrate that the doctor was

informed of the risk of injury and that, if this risk materialised, it is not imputable to the State. Thus, it would be necessary to demonstrate some other elements of negligence to prove service failure.

The reasoning explained by each of the courts ignores the two main functions of informed consent. The first has to do with the fundamental right of all patients to decide on their life and personal integrity, so that it is the duty of all doctors, before any treatment, to provide information on the procedure to be carried out, as well as to request the patient's authorisation about any action that is planned to be performed.

On the other hand, and approaching the basis of the critique, another of the functions of informed consent is to make the patient a co-participant in the medical treatment to be performed. That is, whenever the patient is the one who makes decisions about his or her health and personal integrity, the authorisation that he or she gives to health professionals makes him or her responsible for the risks that he or she has been clearly and sufficiently informed of (García, 2018, p. 146).

One of the logical effects of consent, then, is that the negative results of a treatment, whether therapeutic or surgical, are covered in a scenario of self-responsibility of the patient; after all, it is the patient who decides about his body and personal integrity, so it would be wrong for the law to hold the doctor responsible when he is not the one who makes the decision; he only proposes a treatment and carries it out following what has been informed. Based on the above, it is only natural that only obligations of means arise from medical acts, whereby professionals only commit themselves to use all their knowledge and skills to achieve an end, but this does not mean

that they guarantee it. Hence the preponderant jurisprudential position that medical liability must be analysed according to a subjective regime.

However, if a doctor performs a procedure without informed consent, which means violating the patients' right to decide about their health and personal integrity, does the logic of self-responsibility explained in the previous paragraph hold? The answer is no, since it is not possible to hold a subject, in the case of our example, the patient, is responsible for an act that is not attributable to her and that was deliberately performed by the health professional.

Then, when a doctor, having the obligation to do so, does not obtain the patient's informed consent for the performance of a procedure, the latter must assume, in terms of liability, the realisation of the risks produced by the act performed, as would be, in our example, the surgical injury suffered by the patient. This is provided that medical activity, whether we like it or not, in certain cases involves risks and, therefore, is susceptible to being analysed based on a strict liability regime. To conclude otherwise on this point would be to disregard the fact that people have the right to decide about their health and personal integrity. This is one of the reasons why obstetric violence is a recurrent practice in Latin American countries, as there is no incentive for health professionals to obtain the authorisation of patients before performing any procedure.

Now, it is true that in some judgements of the Supreme Court of Justice, medical activity was erroneously qualified as - *per se* - a dangerous activity (C. S. J., Civil Chamber, 14 March 1942 and 14 October 1959), for which I adhere to the criticisms that were made on such a postulate, but not on the same grounds. In debating these decisions, the doctrine

resorted to arguments that the profession of medicine is based on ethical-social, "do-gooder" and altruistic postulates. It was also argued that, historically, strict liability had been designed only for business activities, but not for professions as worthy and desirable as medicine (C. Jaramillo, 2015, 131-142). To tell the truth, these arguments are not valid today; as a rule, medicine responds to market dynamics, but not to the altruistic intentions of some individuals concerned about people's health and well-being. And when this is not the case, it is the State, through its provision of services, that performs this service. Moreover, strict liability does not apply to business activities, it applies to dangerous activities, i.e., conduct that increases the normal levels of risk, whether they are lucrative. Therefore medicine, as a risky activity in certain circumstances, may come under a strict liability regime.

In short, the arguments aimed at dismissing out of hand the objective regime for medical liability are loaded with a condescension that in legal terms is not relevant, so much so that, in other latitudes, it has even been considered, in a judgement, that the "medical profession has much of a priestly nature" (T.S.E., Civil Chamber, STS 453/1991, 1991), a matter that in a secular country has no relevance whatsoever, however small or large it may be, all trades and professions have the same value in social terms, so that these are not arguments to determine the applicable liability regimes.

Thus, according to what has been explained, the patient in our example could request the application of a strict liability regime, since the doctor, having the obligation to do so, did not provide the necessary information to obtain consent. The lack of the patient's authorisation for the surgery implies that the risk of the medical activity was not transferred so the professional

should be liable for the realisation of any risk arising from the procedure performed.

However, it is important to clarify that medical liability for the realisation of a risk that was not informed and, therefore, consented to by the patient, must be conditioned by the fact that the harm suffered by the patient must be a consequence of the medical activity, not a result of the pathology suffered, a matter that in some cases will imply a judicious and demanding evidentiary exercise. In addition, a doctor or an IPS cannot be judged objectively when the information provided, even if erroneous, complies with the *lex artis ad hoc*, which means considering what the doctor could reasonably have inferred at the time of treating a given patient.

CONCLUSIONS

In short, it cannot be said, *per se,* that the *subjective* regime applies to all cases of medical liability, any more than it can be said that, *per se,* the objective regime applies to all cases of medical liability. This will depend on the factual analysis that each case raises.

Thus, taking into account all of the above, the application of the objective regime to cases of medical liability must take into account the following assumptions: (i) the procedure performed by the treating physician must involve an abnormal level of risk, such as that arising from surgery, (ii) the treating physician or the institution providing the health service failed in its duty to provide clear, complete and sufficient information to obtain the patient's consent, and (iii) the damage for which compensation is sought must be the realisation of one of the risks of the treatment applied, and not an effect of the pathology for which the patient sought the health service.

On the other hand, and in anticipation of a possible criticism of the above, let us remember that for the jurisprudence of the Supreme Court of Justice, all medical liability takes place in a contractual sphere, so that the regime of dangerous activities is not applicable, but rather the classification of the obligations of means and results. However, it is not possible to maintain the above reasoning when in medical practice, informed consent is disregarded, as this would be a fundamental requirement for the existence of any contract. If a patient does not authorise the treatment to be provided, there is no contract for lack of the requirement of consent, so the activities carried out by the physician or the IPS cannot be analysed from the perspective of a negotiated agreement. Consequently, when one wants to hold a subject liable for damage that is not the result of a breach of contract, what is the applicable regime? The non-contractual regime, in which liability for the exercise of dangerous activities does exist.

In fact, in the already explained judgement of 7 December 2020 (C. S. J., Civil Chamber, SC 4786-2020, 2020), the Court indicated that the absence of informed consent engaged the liability of doctors but did not mention in what way. Hence, it could be inferred, according to the current jurisprudential line, that the judge believed that the lack of informed consent gave rise to an obligation of result, but this would be an important logical contradiction since it is not possible to predicate the existence of a contract with the deprivation of one of its requirements of existence: consent. Consequently, attributing a role to informed consent in the liability trial would mean recognising the possibility of applying objective extra-contractual liability in the civil jurisdiction, which would be quite a change in the jurisprudential paradigm.

Thus, in effect, as established in article 26 of Law 1164 of 2007, the health care relationship generates an obligation of means, which applies to the contractual and non-contractual sphere, even though obligations of means in non-contractual matters do not exist, but this is how the Council of State has understood it, which for medical practice and the exercise of administrative functions is quite correct. However, as already indicated, and following the assumptions, the violation of informed consent should give rise to the liability regime for dangerous activities or exceptional risk, both in the jurisprudence of the Supreme Court of Justice and in that of the Council of State. This does not mean that the rule is disregarded since the doctor's obligation is one of the means if the medical act is validated by the informed consent or by the legal exceptions that allow the professional to act without it.

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