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Headquarters:	Barcelona.
Section:	4
Appeal No:	222/2008
Resolution No:	723/2009
Proceeding:	Cassation Appeal.
Reporting Judge:	EDUARDO BARRACHINA JUAN
Resolution Type:	Ruling.

Voices:
INFRINGEMENT OF LEX ARTIS
PRESCRIPTION (CIVIL LIABILITY ACTION)
INFORMED CONSENT

Summary:
Health responsibility. Informed consent,

SUPREME COURT OF CATALUÑA.

ADMINISTRATIVE LITIGATION CHAMBER.

SECTION NO 4

Appeal no: 222/2008

FROM: José Ángel and OTHER

Representation: IGNACIO LÓPEZ CHOCARRO

AGAINST: SERVEI CATALÀ DE LA SALUT and CONSORCI SANITARI INTEGRAL

Representation: JOAQUIN RUIZ BIBAO and ALFREDO MARTINEZ SÁNCHEZ

Ruling no 723/2009

Mr. JUSTICE PRESIDENT:

Mr. EDUARDO BARRACHINA JUAN

Mr. JUSTICES:

Mrs. Mª LUISA PÉREZ BORRAT

Mrs. Mª FERNANDA NAVARRO DE ZULOAGA

Barcelona, on September 18 2009.

SEEN BY THE ADMINISTRATIVE LITIGATION CHAMBER OF THE SUPREME COURT OF JUSTICE OF CATALUÑA (SECTION FOUR), formed for the resolution of the aforementioned appeal, has ruled the following Judgment on behalf of the King.

Mr. Justice President EDUARDO BARRACHINA JUAN has expressed the opinion of the members of this CHAMBER.

FACTUAL BACKGROUND

FIRST.- On February 26, 2008, the Administrative Litigation Court No. 1 of Barcelona, in the Ordinary Appeal no. 216/2006, dismissed the appeal filed against administrative dismissal of claim seeking compensation for damages as a result of the malfunctioning of the *Servei Català de la Salut* – public health service of Cataluña. There was no imposition of costs.

SECOND.- An appeal was filed against the aforementioned Court's decision which was accepted by the Court of Instance, remitting to this Court´s actions and corresponding this judgment to this Section.

THIRD.- The appeal being completely developed, it was finally established the day and the time for the votation and judgment, which took place on September 14 2009.

FOURTH.- All legal prescriptions are fulfilled in this litigation.

LEGAL RATIONALE

FIRST.- The aim of this procedure consists of determining the origin of this appeal filed against the judgment ruled by the Administrative Litigation Chamber no. 1, in Barcelona, on February 26 2008, which dismissed the indemnifying claim of financial liability regarding the birth of the appellant's daughter with microcephaly and this being the reason for the compensatory claim of 450,900 Euros as it is defined in this appeal.

In the contested judgment, the extinguishment for the exercise of this compensatory legal action is appreciable because of the fact that on July 5 2001, Beatriz´s date of birth, the father was informed about the baby's microcephaly disorder and its repercussions due to being an incurable disease. The administrative complaint was filed on October 26 2004, after the deadline established by law. The diagnosis was confirmed on July 11 2001, when the mother was discharged from the hospital. The April 11 2002 medical report from the physiotherapy department also confirmed the analysis and diagnosis. Moreover, it is hereby stated that in September 30 2002, while

undertaking the medical treatment, the St. Joan de Deu Hospital issued another medical report and so, according to this, there is a limitation of action/the action is extinguished.

In the appeal it is noted that the limitation period for bringing any legal action must start since the moment the scope of the damage is known and that, in the dates expressed in the judgment, the impact of the disease was not known because the nervous and muscular system impairments appear for the first time in a report on June 14 2007. In another report dated on June 11 2007, the St. Joan de Deu Hospital confirmed that the scope of Beatriz´s disease is not known yet. The report highlights that this disease is a chronic pathology but unstable, as shown in the cranial magnetic resonance conducted on April 23 2007. The scope of the disease is not confirmed. Moreover, the extent of the deficiency was 33% in the year 2002, 50% in the year 2004 and 75% in the year 2007. The appellant views the resulting damage as caused by the lack of information provided to the parents, who may have chosen between terminating the pregnancy or not. The appellant states that the lack of an ultrasound during the first quarter of the pregnancy period was crucial for the diagnosis of Beatriz´s disease, that there was a bad interpretation of the fetal measures obtained in the ultrasound done in the 22nd week of the pregnancy, and that they there was no other ultrasound or medical test conducted to guarantee a correct diagnosis. They emphasis the lack of detection of microcephaly before the 22nd week and of the irregular fetal growing that was discovered by the second-quarter ultrasound.

The Institute Català de la Salut in its submitted brief against the appeal affirmed that the limitation period for bringing any legal action is extinguished and regarding the merits, that there is no causal relationship. The expert report of Dr. Dimas is included. He is a Specialist in Obstetrics and Gynecology who affirms the inexistence of any behavior that could lead to a violation of *lex artis* or professional duties.

In its written submission, the Consorci Sanitari Integral asks for dismissal of the appeal due to the exhaustion of the time limit, the lack of a causal relationship, and the mycrhocephaly diagnosis already being known at the time of admission to the St. Joan de Deu hospital. The father was informed that this disease was incurable. The Consorci Sanitari Integral also claims that the scope of the disease and its consequences was reported on September 30 2002 because the report from the hospital issued that the girl "suffers a mycrocephaly disease and moderate psychomotor limitations together with osteotendinous reflexes in the lower extremities. She must receive medical monitoring from Early Stimulation Services".

SECOND.- This Court has carried out a joint assessment of both the claims and arguments for the appeal and from the petition for its dismissal and has concluded that the legal action cannot be brought because of the following reasons:

Article 106.2 of the Spanish Constitution states that "[p]rivate individuals shall, under the terms laid down by law, be entitled to compensation for any harm they may

suffer in any of their property and rights, except in cases of force majeure, whenever such harm is the result of the operation of public services”.

The financial structure of the Public Services is regulated by the Law 30/92, Legal Regime of the Public Services and Common Service Procedure. It is an objective responsibility, or according to the results, a responsibility that does not depend on whether the public action was proper or improper. It is enough to demonstrate that the action directly results in the economically quantified and particularized damages, with the constituent elements having been determined in several judgments of the Supreme Court, as shown in the judgment of July 3 2003 that quoted a sentence of the judgment from Mars 7 2000 that notes that this responsibility requires for its recognition:

The reality of an economically assessable and individualized damage related to a person or group of persons who have no obligation to suffer it.

That the damage suffered results from an action of the public services or an administrative activity, leading to a causal relationship.

That the damage has not been produced because of *force majeure*. It is required sine qua non that the causal link between the administrative activity and the resultant damage occurred without any interference that could annul or override it.

Regarding the concerned time-limit exhaustion taken into consideration in the first judgment—a preliminary question in the judgment as it would negate any decision on the merits—we must look to the Supreme Court decision of May 12 2007 that states as follows:

This Chamber has repeatedly pronounced various decisions about the *dies a quo* for the limitation period that can prescribe bringing a legal action regarding financial responsibility. “In this appeal it is questioned whether the determination of *dies a quo* for the limitation period of one year, for actions based on financial responsibility established in the Article 142.5 of the Law 30/92 issued on November 26, is one year after the incident or the act that gives rise to the compensation took place or one year after notice of its damage.

The case-law (judgment dated on December 27 1985, May 13 1987 and July 4 1999 that has been quoted in the judgment dated on July 6 199) understands that the general principle of action nata can be applied in this case. This principle means that the limitation period for bringing any legal action can only start when it is possible to determine both components of the concept of damage, this is, the damage and the verification of its illegitimacy. This criteria was reiterated in the ulterior judgment of the Supreme Court dated on January 21 1991 and on the earlier judgments dated on April 5 1989 and September 19 1989.

To this effect, as indicated in the judgment dated on May 11 2004, the case-law has distinguished between permanent damages and sustained damages in the subsequent judgments of May 12 1997, Mars 26 1999, June 29 2992 and October 10 2002, among others. According to the case-law, permanent damages include those damages in which the cause of the damages has a beginning and an end, even when the resulting damages are lifelong or not subject to change; the sustained damages are those that occur daily and over an extended period without a solution for its continuity, and thus, it is required to allow a sufficient period of time in order to evaluate economically the consequences of this type of damage or its cause. This is why for these damages "the period for any claim will start the day in which the effects stop" or, as the judgment dated on February 20 2001 indicates, in these cases to bring any legal action on financial responsibility the *dies a quo* will be that in which the breaching effects are finally known (judgments, among others, dated on July 8 1993, April 28 1997, February 14 1994, May 26 1994 and October 5 2000).

THIRD.- In this case, the nature of the disease did not allow one to anticipate the possible evolution of the unexpected consequences, but after a certain length of time, the consequences become clear, as revealed by the different reports and tests.

Equally and in the same juridical terms, the Supreme Court pronounces a judgment date on February 28 2007, affirming what follows:

The *a quo* day for bringing a legal action on the financial responsibility has to be that in which the breaching effects are definitely known or that in which the damages are evaluated objectively together with the complete scope of the disease and consequences. Once the scope and the consequences are determined, the subsequent treatments taken in order to provide a better quality of life or to avoid further complications of the disease do not lower the damages, the disease or the consequences.

It is true, as the appellant cites in its well-prepared appeal, that Article 142.5 of the Law 30/92 anticipates that, in the case of the physical or psychical damages, the period established for bringing a legal action on financial responsibility will start from the beginning of the treatment or the determination of the scope of consequences, as the case-law has declared several times and as also stated in the judgment of the Supreme Court of December 19 2006, that "the aforementioned prescription period cannot start until the consequences are completely determined, that is, that the detrimental effects stop or that a stabilization of health is reached (in all the judgments dated on October 4 2004 and October 27 2004 that quotes those dated on April 28 1997 and May 26 1994).

With this aim, it is believed that the appellant can delay the action for bringing a legal action until the moment he definitely knows the scope of the damages suffered, delaying until that moment the start of the limitation period, for the benefit of the appellant in terms of preparing an appeal which includes the reparation of the whole damages resulting from the prejudicial act. This refers to a complete relation, according

to the principle on this matter, that takes into account that this right demands attesting the damage alleged.

If the aforementioned doctrine is applied to this case, we conclude that in the year 2002 the total consequences of the disease were neither consolidated nor known in order to determine not only the medical treatment for Beatriz to undertake but also the rehabilitation treatment to perform. And because of this, it is necessary to get to the bottom of this controversial issue.

In terms only refereeing to the Public Administration financial liability because of the public services offered, the jurisprudential doctrine is also the one to follow, so we quote the judgments dated on Mars 20 2007, Mars 7 2007 and Mars 16 2005, and it says that:

We can only demand the Public Administration apply medical techniques according to the knowledge of the medical practice, without basing this liability in the damage caused. This cannot apply because what is being punished in terms of medical liability is an improper application of means for obtaining the results. In any case the patient may pretend these results to be positive.

In this sense, the judgment from the Supreme Court dated on October 30 2007 states what follows:

The case-law declares that the existence of damage is not enough (because it would raise the objective liability beyond a reasonable limit), but what is required is to turn to the *lex artis* criteria for determining the correct medical action regardless of the consequences for the patient as it is not possible for either the science or the Public Administration to guarantee, in any case, the patient's health.

So, in the judgment dated on October 14 2002, by reference to the judgment dated on December 22 2001, it indicates that the "financial responsibility

Thus, the judgment of October 14, 2002, referencing the one of December 22, 2001, states that "at the Institute of liability of the Administration, the element of the agent´s guilt disappears against the purely objective element of the causal link between the public service conduct and the occurred damaging or harmful result, although, when the health or medical service is questioned, the use of proper technique is a fact of great importance to decide, so that, even accepting that the suffered consequences were caused during surgery, if the surgery was completed successfully and according to the state of knowledge and any post-operative incidence was properly resolved, this constitutes an injury that is not an illegal damage under the legal definition, today collected in the Article 141.1 of Law 30/1992 of November 26th, drafted by Law 4/1999 of January 13th, that confirmed legislatively the traditional jurisprudence doctrine, which Scope has been assayed in this precept. "

Now, in order for the Administration to be responsible to pay compensation for the consequences under the general doctrine outlined in the preceding Background, it is essential that the consequences arise from malpractice by the health service, because as mentioned, the causal link between medical treatment and the harmful outcome is not sufficient, but it is also necessary that the harm suffered by the patient is unlawful because he does not have the duty to bear it. And that, in the present case there is no evidence -not even shown in the expert´s report- that the appellant's infection was a result of medical intervention that was contaminated with sepsis during the treatment process that would reveal malpractice by the doctor who performed the intervention, so it cannot be said that in these circumstances the damage qualifies as unlawful as the intervention was initially performed with a proper technique.

FOURTH.- Furthermore, in terms of Health Administration´s financial liability we must take into account that it is necessary to establish a parameter that provides the means to determine the level of the administrative activity to which the damage is attributed. This is a parameter that allows differentiating those cases in which the damages resulting can be attributed to the administrative activity or those cases in which the damages are resulting from the natural evolution of the disease and the impossibility to guarantee the patient's health in every case.

The basic criteria used by the litigation-administrative case-law to evaluate the existence or not of the financial responsibility is the *lex artis* criteria because of the lack of any other normative criteria that can establish whether the functioning of the public services has been proper.

The usage of these criteria is based on the basic principle underpinned by the case-law in the sense that the obligation of a medical practitioner only concerns the methods and not the results, that is, the obligation only extends to provide the medical treatment and not to guarantee in any case the successful cure of the patient. So, the *lex artis* criteria is a normal standard for the medical practitioner in order to evaluate the correct medical actions and impose the obligation to act according to the due diligence procedure.

This criteria is basic as it allows limiting the cases in which there can be true liability demanding that it does not only exist the damage element but also a lex artis breaching, because in case of demanding only the existence of damage then that would lead to an undesired legal consequence. Liability would be excessively objective if the only requirement for anyone to demand compensation is the existence of effective damage without requiring the showing of a breach of the normal standard represented by the *lex artis* criteria.

The Supreme Court in its judgment dated on June 7 2001 states the following: "The imputation of financial responsibility because of damages derived from administrative action based on proper or improper functioning of public services cannot consist only on the practice of a risk activity, as the appellant understands, but also that

it can lie on other elements, as in the medical services, the inadequate provision of medical care.

This inadequacy, as we will see in the development of this case, can be the result not only of the existence of informed consent but also because of the breaching of the *lex artis* criteria ad hoc or, by default, lack or not sufficient enough objective coordination of the services. From this we can observe that, against what the appellant seems to understand, the existence of informed consent does not oblige the patient to assume any risk resulting from an inadequate medical assistance.

The malpractice alleged by the appellant lies in the fact of not having informed the parents of critical information for deciding whether to terminate the pregnancy. It refers that the lack of an ultrasound in the first quarter of the pregnancy was relevant in terms of minimizing the time and method to diagnose the disease suffered from Beatriz; the interpretation of the fetal measures obtained in the ultrasound carried out in the 22nd week of the pregnancy period was incorrect; the repetition of carrying out other ultrasound and clinical tests was avoided.

The report dated on July 4 2004, issued by Dr. Paloma, specialist in Obstetrics and Gynecology, and analyzed the documentation that the parents had until that moment. In this report, the doctor confirms that it was in 38th week of the pregnancy period when their parents were verbally communicated that the fetus suffered from mycrochephaly; that there was a lack of information provided by Dr. Teodoro regarding this pathology to choose whether to terminate the pregnancy or not; that this doctor carried on the medical tests and even the ultrasounds in its clinical private; that the pregnancy period lasted 299 days instead of the common 280 days; that the optional assistance during the pregnancy period and the birth was against *lex artis* criteria; that doctor Teodoro knew the fetus´s pathology since February 15 2002, but did not inform the parents; that he permitted the pregnancy period to reach to 299 days without a good cause. She finally concluded that all these reasons fostered the disabilities or consequences that Beatriz suffers.

FIFTH.- As both in the appeal and the claim at first instance, it was remarked that the lack of the obligation to report to the parents, so they could have evaluated the option of interrupting the pregnancy because of the pathology suffered by the fetus, we will say as follows:

The reported consent constitutes an obligation imposed by law referred to offering the patient the adequate information about the consequences of the medical procedure, so she can be willingly decide, regarding the considerations exposed, whether she wants to undergo to the medical actions or not. But there is no reason to require a reported consent related to a possible lesion that, in the moment the medical service was being given, its particular etiology and origin.

Article 10 from General Health Law 14/86, expresses that every person has, regarding to the different public medical administrations, among other aspects, the right "to receive in a comprehensive expression, to him/her and her family a whole and continued written and verbal information about the process, including the diagnosis, prognosis and alternatives of treatment" (paragraph 5); right "to free election among the options presented by doctor responsible for her case, being precise the previous written consent of the patient so as to make any intervention", (paragraph 6) except for, among other cases that are not interesting here, "when the patient is not able to make decisions, in which case, the right will belong to her family" (letter b)); and finally, the right "to leave a written record of all the process" (paragraph 11).

According to the informed consent in the field of health it is more and more important the particular forms, as the only way to guarantee that it fulfills its aim is through a wide and comprehensive protocol of the different possibilities and alternatives, which must be controlled very carefully.

The particular contents of the information transferred to the patient so as to get his consent may determine the agreement or rejection of a particular therapy because of the risks that may entail. Nevertheless, it is important to remember that excessive information may turn the clinical attention into an excessive amount of attention, as a clinical act means giving complex and technical information to the patient and an unnecessary suffering by the sick person, who usually does not understand the importance of the information provided.

It is necessary to interpret in reasonable terms a legal precept that if applied with inflexibility, would hinder the exercise of the medical activity or it would make this exercise completely impossible, as the patient may reject too long or inadequate protocols or he may understand this situation as a violation of her subjective rights, without excluding that the previous information may include also the benefits the patient would enjoy if he does what he is asked for and the risks on the other side, when they are clearly known.

Thus, the legal regulation must be interpreted in the sense that it won't exclude in a radical way the validity of the consent about the non-written information.

However, when demanding that the reported consent will be adjusted to this documentary way, more adequate to record its existence and contents, the new regulation of the General Health Law (Ley General de Sanidad) has competency enough to invert the general ruling about the onus of proof (according to which the evidence of the determinant circumstances of the responsibility concerns to who wants to demand it from the Administration.)

The duty to get the reported verbal and written consent bins to understand that, if the duty had been adequately fulfilled, the Administration could have easily demonstrated the existence of such information. It is well know that the general principle of the onus of proof suffers an important exception in those cases in which

there are facts that can be easily proven by the Administration. On the other hand, it is not necessary to require the appellant to prove the lack of information because of the negative nature of this fact, whose evidence would entail a serious difficulty.

However, it is ridiculous to compare a lack or failure of reported consent with an irregular operation of the public service, to use it as a reason of the financial liability, as it would necessarily be synonym of a bad exercise.

In this case, it is important to stay away from general principles and dogmatic statements given that informed consent is never equivalent to success in a medical treatment or in surgery. In the opposite sense, the lack of informed consent cannot be compared in an automatic and necessary way to a bad exercise, which means an inadequate medical treatment or a surgery after which the patient suffers symptoms. An emergency surgery is not the same as one planned with time enough for the patient to understand the importance of the decision of undergoing surgery. Nor is a surgical intervention that does not present any risk, from the very beginning, the same as another one where it cannot be known that the percentage of success is limited or minimum, when an alternative treatment has no or a limited effect.

Thus, the objective and subjective circumstance that attend in each case are the ones that will indicate the legal effect that may produce, in each case and never in a generalized way, the lack or failure of the reported consent, in the sense that whether it could suppose a determinant factor in the financial liability within the provision of the health public service.

It is like this, given that the management of the pregnancy and the assistance during labor was done according to *lex artis*, as it was, with high qualified staff, as it was also, and using the most advanced scientific means and knowledge, the fact that the child Beatriz suffered the pathology already indicated, which later got worse, is impossible, or in procedural terms, inadmissible to relate the pathology with the lack or failure of consent.

The important thing is to determine the measure in which the reported lack of consent appears in the relation of the causality to turn into the determinant factor of the petition for indemnification.

In other words, if the lack of information could limit or hinder the mother's right to choose whether to voluntary interrupt the pregnancy, as the reported consent of this case is singular.

SIXTH.- To analyze and solve this aspect, it is well known that the expert evidence, as another one in the case, expects to complement the knowledge of the judge or tribunal, when adopting a decision whose technical basis or contents, make necessary the contribution of an expert in each of the scientific areas that must present.

In relation to medicine, an inexact and incomplete science, among others because of the actual nature of the human being, "*lex artis*" or the complete scientific knowledge is not always applied that can recover the patient. But such expert evidence cannot bind the tribunal in a categorical way but, as another evidence, it must be valued according to the circumstances given in each case.

Unfortunately, it is true that once damage or even a fatal result is produced, it is easy to establish what should have been done in any moment. But given the way the facts developed from the moment when she went to her doctor, because of the pain the patient suffered in that moment, her condition was examined and she received the adequate treatment, up to the moment when, as the prescribed rehabilitation process was unsuccessful, the decision to conduct surgery was made, but it did not get a successful result either.

In legal controversies like this one, where a supposed fact with enough legal effects to give the basis for a compensable action, but that counts on different decisions from medical professionals, is when the interpretive function plays its role, with the aim to distinguish the possible existence of the requirements of the relation of causality. That is not easy when those decisions come to contradictory conclusions when analyzing the development of facts.

This Tribunal has jointly examined both reports done by professionals in medicine, in relation with the clinical history and assistance both during the pregnancy period and in the moment of labor, to conclude unanimously that there was no bad exercise.

This is like this, given that it has been demonstrated that there was not an infringement of the medical protocol about the toxoplasmosis when considering an option the act of sieving, that the echograph done between the eighteenth and twentieth week unfortunately did not allow the determination of the pathology that the fetus suffered from and so it could not serve either to establish a basis on a possible option to stop the pregnancy, as we should not forget that the detention of a corpus callosum agenesia cannot be usually detected in an echograph done during the twentieth week.

Before this objective facts deduced from the clinical history of the mother, the health care and medical assistance that she received, it is obvious that the lack of information has not any importance in the terrible result in which it is not necessary to insist.

SEVENTH.- Thus, this Tribunal considers that the remedy of appeal is available, in which the legal reasons for third decision are recorded, so we revoke the ruling appealed against, but when trying to solve the heart of the controversial matter by application according to the article 85.10 of the Ley de la Jurisdicción Contencioso-administrativa (Jurisdiction Act), that was not judged in first instance, we dismiss the appeal, without any order to pay costs to the effects forewarned in article 139 of the same legal document.

WE RULE

1º We declare the admissibility of the appeal, we revoke the ruling appealed against in this aspect, but we dismiss the appeal.

2º We do not impose any costs.

It must be notified this judicial decision in a legal way, and checked it must be remitted testimony of the present judicial decision to the original Tribunal for knowledge and implementation.

So, for this ruling, of which an attestation will be enclosed to the main orders, we deliver judgment, we send it and we sign it.

PUBLICATION

This ruling was read and published by the Honourable Judge Rapporteur in the Chamber holding public hearing the 25th September 2009, date in which the ruling has been signed by all Judges who composed the Tribunal. In witness thereof.

However, the expert report of Doctor Dimas, specialist in Obstetrics and Gynecologist, Head of Obstetrics and Gynecologist, appointed at random, also analyzes the documentation and reports about the pregnancy and birth of the mother, referencing the Pregnancy Under Care Protocol of Catalonia and the Protocol of Spanish Obstetrics and Gynecologist Institution, as well as others guides he mentioned. He emphasizes that in the systematic screening of the toxoplasmosis was optional, and that in 2002 it was not recommended; that necessity of realizing three ultrasound during the pregnancy in the 8-12, 18-20 and 34-36 week; referencing the 427 article of the Criminal Code that considers punishable the interruption of the pregnancy after the 22nd week; the girl was born with absent corpus callosus, mycrochephaly and psychomotor deficiency; that the analysis practiced for the cromosopathy screening and neural tube defects is under the risk limits, the alphafetoprotein value was 0.57, which was adequate for the gestational age; that the detection of biometrics under 50 percent in the ultrasound practiced on February 15 2001 did not justify the interruption of the pregnancy; that the detection of an absent corpus callosus is very complex and it cannot be detected in normal ultrasounds in the 22nd week of the pregnancy period; that the ultrasounds carried on the new born girl did not detect any anomaly in the nervous system and that the diagnosis of the deficiency neurology was practiced through magnetic nuclear resonance when she was four months. He sums up affirming that the monitoring of the pregnancy was conformed to the medical protocols and that there is no evidence that revealed the fetus was affected of congenital toxoplasmosis. Moreover, the birth

assistance and the method for the delivery of the child conforms to *lex artis* criteria and is not related with Beatriz´s disease. Finally, he states that the hospital treatment conforms also with *lex artis* criteria.