PHYSICIAN'S LIABILITY TOWARDS THE PATIENT IN THE LIGHT OF THE PROVISIONS OF LAW NO. 95/2006, ON HEALTHCARE REFORM

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Summary:

The legal relationships between the medical staff and patients are established within the activities of diagnose, treatment, cure or just the improvement of the patients' state of health. In this study we intend to analyze the conditions and the legal nature of the medical staff duties, as a starting point in establishing the foundation of this hypothesis of civil liability.

Keywords: *civil liability, doctor, patient, professional error*

1. Domestic and international legal provisions

The fundamental rights of the citizens are their essential rights to life, liberty and dignity, compulsory for the free development of their personality. Title II of the Constitution, is entitled "*The fundamental rights, freedoms and duties of the citizens*" and includes, along with a detailed presentation of these rights, also the guarantees designed to ensure their compliance. Among them, *the right to life and to physical and mental integrity* (art. 22)[2] and *the right to healthcare* (art. 33)[3] are guaranteed. Article 43 of the Constitution refers to the *living standards of the population*, meaning the state is obliged to take measures of economic development and social protection, in order to ensure a decent living therefore para. (2) of this article enshrines *the right of citizens to healthcare in the public health centers*.

A remarkable legislative event, Law no. 95 of 14 April 2006[4] projects as a regulatory object *the public health reform*, considered a "*target of major interest*". Protecting and promoting the health of the Romanian population are high-level

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[2] Art. 22 (1) The right to life and the right to physical and mental integrity of a person are guaranteed. (2) No one shall be subject to torture or any kind of punishment or inhuman or degrading treatment. (3) The death penalty is prohibited.

[3] Art. 33 (1) The right to health protection is guaranteed. (2) The State shall take measures to ensure public hygiene and health. (3) The organization of medical care and insurance system for illness, accidents, maternity and recovery, the control of the practice of medical professions and paramedical activities and other measures to protect the physical and mental health of the person shall be established by law.

[4] Law no. 95/2006 (Official Gazette no. 372 of 28 April 2006) was amended by the following acts: G.O. no. 35/2006; G.E.O. no. 72/2006, as amended and approved by Law no. 34/2007; G.E.O. no. 88/2006; G.E.O. no. 104/2006. Throughout this study, we will refer to this act, invoking *the Law*.

political and legislative objectives, *part of the extensive endeavor of our country's integration process into the European Union*. For the first time the legislature included in one legislative act a consistent regulation of the issues concerning the whole health system in our country, in accordance with the rules of the European Community law, repealing the previous regulations in a great measure. Legislative act of great largeness, with 17 titles containing 863 articles, the law regulates the organization of the national public health system, the exercise of medical professions, the medical liability, the public and private social security, namely the production, prescription and distribution of drugs. Each title includes in the final part provisions relating to the transposition of European Union Directives in the extensive harmonization process of the national legislation with the European one.

It would be proper to mention also the *international sources* which contain provisions applicable to the legal relations in the medical field: *the Universal Declaration of Human Rights*[5], proclaimed on 10 December 1948 by the United Nations General Assembly, *the Constitution of the World Health Organization*[6] and *the International Covenant on Economic, Social and Cultural Rights*. Among the Community acts we appeal to *the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine*, concluded on 19 November 1996 by the Committee of Ministers of the Council of Europe adopted in Oviedo on 4 April 1997 and ratified by 40 signatory states[7].

Law no. 95/2006 is the current legal framework of the exercise of medical professions, as a starting point in the debate of doctrinal and jurisprudential solutions in this area.

Of all the regulations regarding the conditions of exercising the medical profession a rule emerges, with a principle value, rule according to which the physician practices his profession (his art) *assuming personal responsibility for the risks that may arise and, consequently, also the obligation of bearing damages for his patient injury*. This noble profession aims "(...) to ensure health by preventing illness, by promoting, maintaining and recovering the health of the individual and of the community" [Art. 374 para. (1)]. The main coordinates of this activity, as summarized in the Hippocratic Oath[8], in modern wording adopted by the World

[5] The declaration sets out the rights and fundamental freedoms that must be guaranteed to every human being. Art. 5 para. 1 states: *Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, medical care and necessary social services*.

[6] In the preamble to this Constitution, paragraph 4 reads: "*A perfect state of health that a man can attain is a fundamental right of every human being, regardless of race, religion, political views, economic and social situation*."

[7] Romania signed the Convention on 4 April 1997.

[8] "*At the time of being admitted as a member of the medical profession: I solemnly pledge to consecrate my life to the service of humanity; I will give to my teachers the respect and gratitude*

Medical Association in the Declaration of Geneva in 1975, must be *availability, reliability, dedication, loyalty and respect for the human being* [para. (2)].

Any medical decision will have to consider the following criteria: *the interests and rights of the patient, the medical principles generally accepted, non discrimination between patients, respect for human dignity* [para. (3)]. These will be linked to the principles of medical ethics and deontology, aiming for the patient's health and public health.

Article 375 establishes the principle of *professional independence and freedom of the doctor* and *his right to decide on the measures applicable to the patient care*. This principle applies regardless of the organization of the healthcare unit, either private or public healthcare unit. Doctor-patient relationship must be based on full trust, information, so that any action must respect the will of the patient and his right to refuse or stop the medical intervention. The article expressly states that "*medical liability ceases if the patient does not comply with the prescription or medical recommendation*" [Art. 376 para. (2)][9].

Title XIV of the Law is devoted to the profession of *pharmacist*, the one performing the preparation of pharmaceutical forms of drugs, manufacturing, control, storage, preservation and distribution of medicines. Professionalism, dedication, reliability, availability and respect must characterize its activity (Art. 559).

Duties falling on the *physician-employee* are set out in Art. 151 of the Code of Professional Ethics, which states that the doctor who is bound in the exercise of his profession through a contract with an administration, a local authority or any other public or private body, *assumes all his professional and moral obligations, individually, including the professional secrecy and the independence of its decisions*. Under no circumstances a physician should accept the limitation of his professional independence.

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that is their due; I will practice my profession with conscience and dignity; The health of my patient will be my first consideration; I will keep the secrets that are confided to me even after the patient has died; I will maintain by all means, honor and the noble traditions of the medical profession; My colleagues will be my sisters and brothers; I will not allow considerations of nationality, race, religion, party or social status to intervene between my duty and my patient. I will maintain the utmost respect for human life from its beginning and even under threat and I will not use my medical knowledge contrary to the laws of humanity. I make these promises solemnly, freely and upon my honor.

[9] Similar regulations were adopted in relation to the profession of dentist, separate from the medical profession, by invoking the provisions of Directive 78-686-EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the dentist titles and of the *Code of Ethics* specific to this activity. We retain an indication of the increased risk of bio-contamination of this profession for which certain facilities are granted [Art. 472 para. (2)].

2. Conditions of the physician's liability towards the patient.

Establishing the foundation of medical liability has in view the fact that the obligations of the physician towards his patient are circumscribed to the sphere of the professionals' duties, compared to which the requirements regarding the quality of the medical care are high. This is the reason why we will try to analyze the nature of the legal relationship between physician and patient, respectively specifying the physician's source of obligations.

The social relationship governed by the legal norm on the fulfillment of the medical act by the specialized personnel for disease prevention, medical care and treatment of the patient in order to cure or improve his health by establishing reciprocal rights and obligations, of which compliance could be ensured, in need, with the support of the coercive force of the state, is a *medical legal relation*[10].

However, which is the source of these duties? *The unlawful culpable act of the physician* consisting of the violation of the physician's obligations to care for and treat the patient or *the non-compliance with the duties assumed under a contract with the patient*?

The establishment of the legal nature of the duty, tort or contract relation, has consequences in terms of delimitation of the culpable conduct of the responsible person and the extent of the damage repair.

Thus, if the patient is dissatisfied with the care provided by the physician and was deemed prejudiced if he appeals to the *physician's tort* under the provisions of Art. 1357 Civil Code, he will have to prove the committing with guilt of an unlawful act or illicit omission circumscribed to the physician's professional duties, in causal connection with the result of the damage produced. The patient will be entitled to compensation both for the predictable damage and the unpredictable damage. The impossibility of proving medical negligence or the lack of causation will be circumstances designed to remove the legal liability of the physician.

If, however, he will appreciate that there is an agreement of intent to grant medical care between him and the doctor, therefore a contractual relationship, the producing of the harmful result will be the definite proof of the intervention failure, namely the contractual fault of the physician who will be required to compensation, but only to the extent expressly provided in the contract wording.

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[10] Regarding the definition of the legal relationship in general, see *Gh. Beleiu*, Drept civil roman. Introducere in dreptul civil. Subiectele dreptului civil [Romanian Civil Law. Introduction to civil law. The subjects of the civil law], 4th edition, Șansa Publishing House, Bucharest, 1999, p. 76. This definition detaches the main features of a legal relationship: it is *a social relation*, being established among people either viewed individually or organized in various associative forms, with or without legal personality, it is a *volitional relation* as it incurs through the free will of the parties, and they are on equal legal footing. Whatever particularizes the legal relation are the parties, the content and the subject.

On this issue the following opinions were made[11]:

a) *The physician's liability is of tort nature*. The medical profession is exercised autonomously and independently, reason why the legal doctrine of our country[12] considered that the physician's liability who practices his profession in state health institutions, for damages caused to his patient, is an *extra cotractual liability*. Between them there is no agreement of will, because the patient does not choose his physician. Therefore the physician is liable independently, personally for all the damaging consequences for his culpable act as he performs his activity "(...) not based on specialist advice given by health unit management, but independently, based on his training in the profession"[13].

The legal grounds of the physician's liability and of other participants in medical act used to be, in the absence of a special law, the provisions of Art. 1357 Civil Code (the corresponding Art. 998-999 Civil Code of 1864), each of them being liable for damages caused by committing illegal acts on the life and health of the patient.

The supporters of this orientation have also considered that between the physician and the health unit there is no subordinate relationships; the latter is not a "civil responsible party". Even in situations where he is the employee of a health unit, he exercises his profession freely. Only some of physician's duties regarding the fulfillment of job responsibilities, such as visits and the second visits, compliance with the working schedule etc., would constitute duties which could involve the liability of the health institute in the capacity of principal. Unlike physicians, all the other participants in medical act are considered to be in a subordinate relationship with the health unit.

b) *A mixed contractual liability*[14], in the case of healthcare provided in private clinics and state health units, either free or paid, under a contract of medical service and of *tort nature*, if the physician caused an injury through

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[11] We note that our legal doctrine in the last decades shared the classification of civil obligations as *obligations arising from legal acts, respectively* of unilateral acts and contracts and *obligations stemming from the legal facts*. In this regard, see: T. R. Popescu, *op.cit.* p. 20; I. Albu, *op.cit.* p. 83; L. Pop, *op.cit.* pp. 19, 28. In a recent paper, the author L. Pop proposes a subdivision of civil obligations arising from legal *obligations arising from human facts-conducts*, namely licit and illicit acts and *obligations arising from facts that are not human conducts* - L. Pop, *Tratat de drept civil. Obligațiile*. [Treaty of civil law. Duties.]Vol. I, *Regimul juridic general*, *cit.supra*, pp. 27-28.

[12] E. Lupan, *Raporturile juridice de protecția mediului de viață al populației* [The legal relationships regarding the living protection], Dreptul no. 12/1997, pp. 7-15; R. Ozon, E. Poenaru, *Responsabilitatea profesională și socială a medicului*, [Professional ad social responsibility of teh physician] Ed. Medicală Publishing House*,* Bucharest, 1973, p. 154 and ff, quoted by *A. Corhan*, *op.cit.,* p. 122.

[13] C. Stătescu, C. Bîrsan, *op.cit.*, pp. 260-261.

[14] L. Pop, *Drept civil român. Teoria generală a obligațiilor*,[Romanian Civil law. The overall theory of duties] p. 269.

inadequate and free healthcare, when the liability of the health unit as a principal may be invoked. The argument for this opinion is invoked in the Decision no. 114 of 1989 of the former Supreme Court, criminal chamber[15], which referred to "*the obligation they* (health units – our pointer) *have to guarantee compensation to those who suffered through the actions committed by their subordinates in the normal exercise of the specific tasks assigned to them*."

The physicians who practice their activity in clinics or private health units are liable *on the contractual grounds*, as the patient requested and agreed with the offering of health care, engaging to pay for the services provided. In most cases, the liability has been engaged on tort grounds and the patient was required to prove the medical negligence.

c) *The physician's liability is contractual in nature*. After the emergence of social health insurance legislation, a reliance on the contractual grounds of medical liability was tried[16]. Thus, it was appreciated that regardless the healthcare is provided in state or private health units, a contractual agreement is established between the physician and the patient by the agreement regarding the treatment or interventions' establishment, needed for the cure or the improvement of his health.

The healthcare contract is a qualified civil contract for services, *intuitu personae*, with a specific content, different from the contracts of this kind, called "classic". In support of this direction, the provisions of Law no. 145/1997 are invoked on social health insurance[17], according to which the policyholders have the freedom to choose the doctor for their medical assistance. The health services providers, the physicians and the health care providers, the health care units, the medical centers and diagnostic treatment, hospitals and other medical units operate under contracts with the health insurance funds.

Thus, it was noted that social health insurance system is compulsory and operates in a decentralized way, based on the principle of solidarity and subsidiarity in the collection and use of funds. Health services providers, including doctors and medical staff, conclude annual contracts with the health insurance fund, to which the insured person has an obligation to pay a monthly contribution. The framework contract regulates the rights of the policyholders and the healthcare conditions[18].

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[15] Dreptul no. 8/1992, pp. 56-58, with the approving note of the author *I. Lulă*.

[16] J. Penneau, *La responsabilité médicale*, édition Sirey, Paris, 1977, pp. 18-25, and in our legal literature: Ş. Beligrădeanu, *Răspunderea civilă a medicilor şi a unităţilor sanitare*, [Civil liability of the physicians and health unities] Dreptul no. 3/1990, pp. 5-11; A. Corhan, *Repararea prejudiciului prin echivalent bănesc*, [Repairing the damage by money equivalent] Lumina Lex Publishing House, 1999, p. 122.

[17] Official Gazette no. 178 of 31 July 1997.

[18] A. Corhan, *op.cit.,* p. 124.

The supporters of this opinion admit that it is possible to engage liability on tort grounds, but only when the doctor or the medical staff commits a criminal act or when the healthcare is granted without the consent of the patient, unless when acting in an emergency, to protect the public health.

Among the objections made to these guidelines were the ones relating to the lack of proper contractual relations, meaning that choosing a physician does not amount to expressing an agreement by the patient through the conclusion of a contract. The insured patient does not pay for the services directly to the physician, as it would be proper in the execution of his own obligations. Moreover, there is a category of people who, although they do not contribute to the fund, they benefit from medical assistance, the payment of the medical services being carried out by insurance funds from special funds budget allocated for this purpose, funds which are not achieved exclusively from the contribution of the insured, but also from the contribution of natural and legal persons employing the salaried staff. Consequently, the prevailing opinion was that of the tort liability in what concerns the physician and medical staff.

After the emergence of Law no. 95/2006 on healthcare reform, it was appreciated that any dispute on this issue must stop in front of certain express provisions relating to *the patient's informed consent*, provided by Art. 649 and *the obligation of ensuring medical care,* provided by Art. 652.

Whenever the medical intervention is deemed necessary, by the patient's consent – after a prior information about the risks he exposes himself – *a legal contract relation* is born where a physician is obliged to exercise his professional mastery with diligence and caution, to obtain healing or just improve his patient's health. The physician has the obligation to provide medical assistance and specialized care only if the patient accepts. In the absence of consent from the patient, the physician will not be able to intervene, but will be required to inform the patient of the consequences he would be exposed to. In case of an emergency, their duties subsists even in the absence of consent, if the lack of assistance may endanger seriously and irreparably, the patient's health or life. Any discrimination between patients is forbidden. The payment for the performance is made directly or indirectly via the health insurance funds.

As far as we are concerned, we consider that in the medical field the strict framing of the legal relationship between physician and patient in a category of civil obligations established by the traditional criterion of the source's appearance, is not possible. Thus, in our opinion, the physician's liability can not be classified in any of the forms of liability, tort or contract liability, because it is a professional responsibility, specific to the medical field, which has a proper regulation according to Law no. 95/2006,.

To support this idea, we must consider two essential criteria:

a) *the special situation of the parties*. While practicing his liberal profession, the physician, as debtor of the obligation of care, must combine scientific knowledge gained during his career with the result of the latest studies published in international journals on the respective disease. Assessing the quality of medical care should be made after the applicable standards (called "protocols") at the time of intervention in this area.

On the other hand, the patient, the creditor of this obligation, is entitled to the protection of his life and body integrity, the right to security. His confidence in the physician's knowledge is circumscribed to the knowledge of the inherent risks and their conscious assumption. From this point of view, the agreement between the physician and the patient is not just a simple agreement, specific to a contract, but takes into account considerations of social equity regarding the exercise in the society of a profession in compliance with all the rules, in order to eliminate the risk of harming the citizens.

It follows that, in the medical field, more than in any other field, the patients' need for safety is important, being a profession devoted to their lives and health, so that the question of legal liability must be adapted to these circumstances.

b) *the content of the legal relationship*. The fulfillment of medical duties depends on a number of factors, primarily of objective nature, which customizes this field of activity. Thus, the medical intervention depends to a lesser or greater extent on the therapeutic random factor. The eventual failure can not be attributed in any case to a crime or breach of contractual obligations. Each case has its particularity, which gives a degree of difficulty in the diagnosis and therapeutic decision making. The correct, certainty diagnosis is the anatomical pathological diagnosis which can be obtained only after an intervention. The doctor should determine the nature of the intervention, and until this moment he should initiate all investigations to decide the diagnosis as close as possible to certainty. The doctor's decision depends, therefore, on the particularities of the case as well as on his skills in solving it.

Patient information includes introducing therapeutic alternatives by specifying the risks and side effects inherent to each of them. Thus, the informed patient will be able to take decisions for himself regarding the choice of the appropriate treatment. Medical responsibility ceases when the patient does not comply with the physician's guidelines, tips and advice. The patient knowingly assumes the risks of the decision about his treatment.

Although the two traditional guidelines regarding the nature of the obligation relationship between physician and patient present convincing arguments, we do not share their views on the existence of a strict tort or contractual relation. The question of medical liability must be addressed in a *field*

of specific professional liability, qualification according to which we shall analyze the conditions of its engagement and its foundation[19].

The physician's liability is therefore the responsibility of the professional to the risks inherent to his activity performance, a special liability, aggravated in relation to other legal liabilities.

The extensive process of "*reconstructing*" the civil liability implies thus, the acknowledgement of a new liability, the third category, which groups the independent rules of the *professional liability*[20].

By its nature, the medical profession is a liberal profession based on the following principles: *the freedom of the medical act*, being exercised without any administrative or any other constraints; *the free choice of employment* by the physician and *the manner of practice*; *the free choice of the physician by the patient*; *the freedom to prescribe medicines*, and also the fact that *the physician is not a public servant*. Naturally, special rules regarding the conditions of holding civil liability must be applied to this liberal profession.

This liability is characterized by the increased requirement to the quality, promptitude and efficiency of the activities carried out by professionals in the field, on the one hand, but also by the increased protection administered to the patient on the other hand. In exercising "his own mastery" to fulfill the duties of care, security, information and advice to his patient, the doctor deploys an intense intellectual activity, involving, along with a thorough professional culture, and a lot of skill, insight in performing certain interventions as well as tact, diplomacy and authority in leading his entire team.

3. The main professional obligations of the physician

The main purpose of exercising the medical professions, particularly the physician one, is to *ensure the health of citizens*, primarily through disease prevention, then investigation, diagnosis and implementation of interventions to cure or improve the health of the patients for their reintegration in the social life[21].

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[19] In the French legal literature, the idea of *professional liability* was supported by prestigious authors: G. Viney, P. Jordain, *Les conditions de la responsabilité*, pp. 323-328 and *G. Viney*, *Introduction de la responsabilité civile*, n. 243; Fr. Terré, Ph. Simler, Y. Lequette, *op.cit.*, 2005, p. 973.

[20] We show that in other areas as well, such as the consumer's protection, the professional liability was invoked, as a distinct category, according to the field of activity.

[21] Code of Ethics of the College of Doctors, Art. 82-85, provides the most important duties of the doctor towards society: the obligation to care for the compliance with the rules of hygiene and prophylaxis, signaling the patient and those around him their responsibility in this regard; the obligation to make known to the public any situation likely to affect the health of the community; service obligation to participate in the call, day and night; obligation to support any action taken by the competent authorities in order to protect health.

A. The physician's obligation to grant care to the patient

The main purpose of the medical profession, according to Art. 374 para. (1) of Law no. 95/2006, is that of "(...) ensuring the health by preventing illness, promoting, maintaining and recovering the health of the individual and the community". This goal is achieved primarily through patient care and medical assistance.

As we mentioned, the practice of a medical act involves in almost all circumstances, *a random factor*, namely the possibility of occurrence of an event that may cause worsening the patient's state of health, regardless the skill, thoroughness and accuracy of the practitioner. For this reason, this obligation is qualified traditionally "*by prudence and diligence*" because the doctor has the duty to submit all the perseverance required by ethics and medical science, so that the desired result – the healing or the improvement of the patient's health – to be achieved. Failing to achieve the anticipated result does not mean that the physician failed to fulfill an obligation and this can not be the proof of his culpable conduct. Only when the patient, as a creditor of the duty of care, will demonstrate that, in exercising its powers, the physician has culpably violated the obligations corresponding to him, may require the physician to hold liability. The foundation of the physician's liability for fulfilling this obligation is, in most cases, his proven professional negligence. Only exceptionally it can be an obligation of result, when the medical care is completed by producing a certain result.

The case law has synthesized the main criteria of a medical culpable conduct:

- *intentional deceptive guilt* committed with the intention of producing harmful consequences, in exceptional situations which usually combine the integrant elements of an offense;
- *professional misconduct due to inaptitude, ignorance, incompetence* consisting of the breach of duties regarding the improvement of professional competence;
- *professional negligence or improvidence* recklessly by failing to take all usual precautions to avoid risk of producing an injury;
- *professional misconduct by negligence or lack of interest*;
- *professional misconduct by easiness* when the physician acting on his patient, although aware of the potential risks, carelessly hopes that the damaging results will not occur;
- *guilt by omission* whenever the physician refuses to give medical care and does not act, although it was his duty to avoid injury;
- *guilt for unauthorized practice*;
- *physician's guilt on his patient's rights* for the breach of the patient's confidentiality, incorrect and incomplete informing of the patient, failure to obtain his consent.

B. The duties of safety towards the patient

One of the main duties of the physician is the safety obligation for his patient consisting of the *organization and leadership of the care for the patient's healing by preventing and removing any risk of injury throughout the performance of the medical act, by respecting the patient's right to physical and mental health*.

According to its specificity, the professional activity in the medical field, especially within the surgical and interventional activity, can generate a risk of bodily harm during healthcare and treatment. In this sense we can exemplify: neurosurgical intervention by which the sciatic nerve was damaged, leading to paralysis of the left leg, making an evacuation puncture to patient with ascites resulting in vessel injury leading to haemoperitoneum with the risk of death, the intervention made in the breach of aseptic and antiseptic rules which creates a risk of infection, the performance of a computed tomography scan with contrast material to a patient with chronic renal failure, as this aggravates the patient's condition through its elimination, the administration of anticoagulants to a patient with a gastrointestinal bleeding history having consequences like hemorrhage recurrence with the risk of perforation and of pancreatitis.

In this regard, the medical intervention is justified only by obtaining the recovery of the sick person or just by the improvement of the patient's sate of health, having in view the settled diagnosis. The patient agreed in full knowledge, assuming only the risks of this intervention. In case of the occurrence of harmful consequences for the patient, unrelated to the disease progression, a negative effect was obtained, injurious, contrary to the purpose of the intervention, for which the doctor will be held liable.

In some cases, the harmful outcome is produced by performing a dental implant by using an improper material, the application of a prosthesis or a faulty device. To obtain compensation, the victim may invoke the liability of the dentist for breach of safety but also liability for defective products or things, the doctor being the supplier of these products.

The need for an adequate legal framework to ensure the repair of the damage suffered by the patients led to the invocation, in certain jurisprudential decisions in the last decades, of the breach of the duty of safety[22]. In these circumstances, the "discovered" obligation over a century ago, in some contracts, such as the transport of people, was recognized also in the content of the medical legal relation.

[22] Regarding the history and evolution of the obligation of security in doctrine and case law, see: L. Pop, *Discuții în legătură cu unele clasificări ale obligațiilor după obiectul lor*, [Debates upon some classifications of duties according to their object] Dreptul no. 8/2005, pp. 73-75 and I.F. Popa, *Obligația de securitate – mijloc de protecție a consumatorului*, [The duty of safety-means of the consumer's protection], Dreptul no. 3/2003 pp. 71-73.

According to Art. 373 para. (3) of Law no. 95/2006, "The decisions and judgments of medical nature will be taken in the best interests and rights of the patient, the medical principles generally accepted, the non discrimination between patients, the respect for human dignity, the principles of ethics and medical ethics, the healthcare for the patient and the public health".

All criteria listed in the legal text that should guide the medical activity shall consider, firstly, the respect for the interests and rights of the patient. For this reason, it is natural that the patient's harm of bodily integrity or even his death due to causes other than his illness to be considered breaches of security, the doctor has for his patient.

In order to pronounce on the fundamental nature of this liability for the breach of security duty by the physician towards his patient, we consider it necessary to examine the different types of risks that can occur during medical intervention.

a) Following the possibility of anticipating the harmful results, there may be *risks subject to norming and risks not subject to norming*. The first category consists of the risks likely to have an advanced assessment, which can be prevented, controlled. Responsibility must be based only on the ignoring of the known risks, which are avoidable. For example we may invoke the following situations: administering postoperative antibiotics to prevent the risk of wound infection, anticoagulation in case of atrial fibrillation that prevents the risk of strokes or avoiding hepatotoxic medication in patients with liver disease, as circumstances in which the risk can be known and therefore controlled.

At the other extreme there are the totally unpredictable risks, occurrence of which depend on random factors, largely unknown to the medical sciences researchers. In this category we can call on the cases of sepsis as the result of localized peritonitis, cerebral hemorrhage occurred in conditions of an undiagnosed aneurysm up to the moment of bleeding or the incompatibility of the transplanted organ by the recipient's body. The scientific research level does not provide methods and practices to prevent or avoid such risks. The harmful result occurs not only independently of any culpable conduct of the physician, but also independent of the state of scientific knowledge in this area. At this level, the medical liability must cease facing the fatality of destiny.

b) According to the legitimacy of risk criteria, there can be *justified risks (useful) or unjustified risks (useless)*. The disclaimer of useful risks is a serious medical error that concerns the professional incompetence of the physician and may lead to his responsibility for harmful consequences produced. The state of necessity involves correct assessment and the acceptance of useful risks. In principle, any surgical intervention is subject to a certain risk. The physician's duty is to weigh the risk of *performing the surgery* in balance with the *risk of non performing the surgery* as his liability can be incurred if he doesn't perform the

surgery has to or if he performs an unjustified intervention. In most cases of aesthetic surgery there is no justified risk concerning the health of patients, only their desire to improve their appearance.

An elderly cardiac patient, with multiple diseases presents a postoperative eventration after an intervention for duodenal ulcer which is asymptomatic. In his case, the surgery presents more risks than not performing it. Gallstone disease poses numerous risks including that of acute pancreatitis, particularly serious for the patient. Therefore the detection of calculi attracts surgical indication, as this risk may produce at any time, unpredictable and independent of the physician's decision, so that surgery is justified.

c) Depending on the professional competence, *the medical risks may be circumscribed strictly to the physician's specialization or beyond*. Thus, the practice of certain medical actions unconsecrated and dangerous for the patient attracts physician's liability for the harm produced.

As for us, we believe that the physician's liability for the violation of the duty of safety to his patient can be engaged only when he ignores *the risks subject to norming, justified and circumscribed to his profession and specialization*. All other dangerous circumstances are absolutely unpredictable of objective, exceptional nature, which can be assimilated to a case of force majeure in order to remove the physician's liability.

Physician's liability as a result of the violation of the safety duty for his patient, in our assessment, must be *based on the idea of guarantees on controlled risks, justified and useful, occurred in the exercise of his profession, a foundation of objective nature, a legal liability "of total justice"*.

The main duty of the medical legal relation, that of offering health care, exposes the patient to particular risks of harm, to which he would not normally be exposed in other situations. Hence the requirement that the doctor performing the diagnosis and intervention should take all measures to eliminate these risks and avoid, as much as possible the damage of the patient. In this sense we must raise *social equity* considerations regarding the performance of the medical profession with the duty to keep a close watch on the safety of his patient, in the event of certain activity risks that his medical activity carries[23]. The significance of consecrating the security duty of the physician and the establishment of its legal nature are particularly important in terms of substantiating the physician's liability.

Considering that in our jurisprudence no judgments were ruled that motivated the failure of the physician to comply with his obligation to safety for his patient, the jurisprudence being constant in the exclusive examination of his

[23] In this sense, see G. Viney, P. Jourdain, *Les conditions de la responsabilité*, 2006, p. 470.

guilty conduct by appealing to the subjective substantiation of this liability in the following, we will exemplify with judgments from the French jurisprudence.

Thus, in the last decade of the last century, the French doctrine and jurisprudence considered the obligation of security as an *obligation of result*. All the harmful consequences of the medical act represent the actual proof of the breach of this obligation, which attracts the physician's liability, independent from his subjective attitude. By adopting this interpretation, the courts[24] decided the engagement of the medical liability, *in the absence of any fault*, by considering the non-compliance with the duty of safety for the patient.

As for us, we consider that the highlight of the legal nature interpretation regarding the obligation to safety for his patient is necessary in relation with the *nature of risks assumed* that caused that injury.

We must take into account random factor involved in the medical activity, which may lead to worsening of the patient's health or even his death, independently of any professional error of the practitioner. This should be circumscribed only to *controlled risk taking, fully justified, legitimate and useful, appropriate to the medical specialization*. To the extent that the action or inaction of the physician by which the integrity of the patient's body was injured demonstrates his incompetence, ignorance, negligence, ease or imprudence, by ignoring these risks widely known at the present level of scientific research, it is natural to consider that an *obligation of "outcome"* was violated regarding the safety towards the patient. *The physician's liability will be trained on the idea of the risk regarding the professional activity in society*.

For supporting this orientation we have in mind the fact that the physician's professional activity is primarily humanitarian, the harm to the patient during surgery or medical treatment being unacceptable. Performance aims at life saving and patient's recovery, and in order to achieve this objective the physician must act with prudence and caution, using all his skill and experience and of his fellows. If by the act of care the patient was seriously harmed or died, it means that the obligation of exercising the profession safely, by eliminating the unjustified, unnecessary risks, was violated. Any surgery, treatment, investigation or diagnosis involves and patient's safety. The result is materialized by producing harmful consequences, unwanted, other than those concerning the patient's care.

In dangerous situations regarding other occupational hazards, *the non-standardized or uncontrolled, unjustified and uncircumscribed hazards of the profession*, the physician's duty of safety towards his patient is of "*means*" in the sense that liability will be triggered only if his culpable conduct linked to the outcome of harmful produced can be proved. We consider these existing

[24] Court of Cassation civil section, Decision of 8 November 2000, *La Semaine Juridique*. Édition générale (J.C.P.G.), 2000, II, 10493 with observations by G. Viney.

jurisprudence judgments which suggest that in such cases it is an obligation "*of result*", profoundly unfair, as these judgments violate the fundamental principles of civil liability, based on the idea of *professional misconduct*, transforming this noble profession into an activity of sacrifice in order to satisfy the claims of medical accident victims, sometimes exaggerated and unjustified.

C. The duty to inform the patient

Protecting patients against the risk of professional activities carried out by health care specialized and authorized providers concerns also the correct disclosure of information on the content and conditions of care[25]. Thus, one of the physician's professional duty, regulated in Art. 649 of Law no. 95/2006, lies in the *correct, complete and understandable information given to the patient or by his express request, to his family members or other designated person, on his state of health with respect to diagnosis, investigation, prognosis and, in particular, the risks that can occur when applying a certain treatment or performing a surgical procedure with the recommendation for medical care deemed necessary*.

The patient's right to take a decision vital to his life and health is linked to the correlative duty of the physician to inform his patient fully and competently to avoid all possible risks. This obligation is professional-related and envisages the transparency of the medical decision, the need for loyalty and the good faith of the parties' legal relationship in order to achieve the objective, namely healing the sick person. Given the fact that his act of informing regards the healthcare activity, the obligation was estimated as *ancillary* to the main obligation of care and treatment.

The correct information given to the patient is conditioned by the physician's act of disclosing information regarding his patient's state of health. Any erroneous information or lack of information essential to establishing the treatment may have adverse effects, which is why it is considered that there is a *mutual obligation to provide information for the physician and for the patient*.

The human personality is seen as a whole, respectively the corporality of the body and its spiritual existence in an indissoluble union. Our legal doctrine was devoted to the idea of respecting the rights of human personality, showing that "*Each individual is largely the master of his body; but this power is limited to public order and good morals*". Any unlawful act designed to harm the bodily integrity or cause death should be sanctioned, because "*the human body is an inviolable sanctuary*"[26].

The patient's consent represents a decision on his life and bodily integrity by establishing the correct diagnosis, by choosing an appropriate treatment or an

[25] G. Viney, P. Jourdain, *Les conditions de la responsabilité civile*, 2006, n. 549.
[26] O. Ungureanu, the quoted article, p. 15.

adequate intervention for his recovery and healing. Due to its special significance, this agreement must be based on competent information given by his physician.

In the following we intend to present *the content of the duty to inform*, its legal nature for analyzing the basis of the physician's liability. The physician's act of disclosing information to his patient circumscribes the following: presentation of the current state of health by determining the diagnosis, indicating the treatment the patient needs and the conditions it can be performed, the risks he will be exposed to in case he will not follow the recommendations. Information given to the patient should be simple, clear, on his understanding, adapted to the level of intellectual and socio-cultural development, professional and complete, thoroughly substantiated. After receiving this information, the patient expresses his consent - called "*informed consent*" - on medical care or the intervention he will be subject to.

The proof of the duty to inform is the responsibility of the physician, who will present the document signed by the patient, by which he has informed the patient on all necessary information. The written form of the act provides the opportunity to demonstrate the conditions and contents of information, in case of dispute, aspects that can be used as evidence. In case of a damaging event, the patient will prove the causal link between the lack of information and the detrimental consequences which have occurred in order force the physician to repair the damages. On the other hand, the patient's refusal to follow the recommended treatment must be recorded in writing, as a proof in the situation of his health worsening and damage due to his own facts.

A special situation is encountered in the aesthetic surgery, when the patient, without being sick, wants a change in his external appearance. In this case, the physician's recommendations must target the potential dangers the patient exposes to, by performing the surgery, with all the possible consequences on his health.

A controversial issue continues to be the one of the assessment *in concreto* of the exceptional and unpredictable nature of the risks to which the patient is informed. In principle, such risks have not been brought to the attention of practitioners, as they have not been discovered yet. If the risks are known but no scientific method has been established for their removal, the patient must be informed. Thus, in a case involving an antibiotic prescribed to a patient, which led to a coma, the French courts[27] have held that "(...) the risk of that allergy was not known to practitioners, being unpredictable after the preoperative and pre-anesthetic examinations practiced, in the absence of allergic antecedents", removing the responsibility of the health unit for the consequences produced.

[27] Court of Cassation civil section, Judgement of 15 June 2004, n. 02-12530, apud G. Viney, P. Jourdain, *op.cit.*, 3rd edition, 2006, p. 486.

In the French case law of the last decades, judgments were pronounced on the physician's liability for the breach of the duty to inform his patient, highlighted through the assessment of its legal nature[28].

The lack of information for the patient, in principle, can not cause damage directly and immediately, as the bodily injury or the death of the patient is in a causal relation with the treatment and the care granted to him. However, the damage to the patient for the loss of the opportunity to avoid *the risk of damage is possible either by choosing the necessary medical care, either by refusing the administration of a particular treatment or choosing to be subject to the hazardous intervention which has been proposed by the physician*.

As far as we are concerned, we appreciate the attention paid to the way of fulfilling the physician's obligation to inform his patient, which is not just a simple act of courtesy, but an essential element for his life and health. The decision to undergo the medical act is largely influenced by the data and information communicated. This involves consciously assuming the foreseeable, useful and controlled risks of the intervention or treatment. In other words, the patient's exercise of the right to decide upon his life and bodily integrity is conditioned by the accurate, complete and competent information. We must take into account the causal link between patient information and its right to make a decision about what is going to happen, and not the relation between the injury and the treatment provided to him.

The legislature has regulated "*the informed consent*" of the patient by setting strict rules on its conditions and contents. In the lack of the informed consent, the physician has no right to intervene as he would be completely liable for the harmful consequences that will occur.

Seen in the light of these arguments, we believe that the obligation to inform is an obligation "*of result*", of which violation can attract the physician's tort on objective grounds, namely *the risk of exercising his profession*. Between the physician's omission to inform his patient on the event of postoperative complications or death, and his inability to make a fully conscious decision about taking such risks, in the event of the injurious result there is a causal link, therefore the physician will be liable.

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[28] In this regard, TGI Paris, 1st civil section, 9 September 2003 n. 01-17420, invoked by G. Viney P. Jourdain, *op.cit*., 3rd edition, 2006, p. 487. Tribunal de Grande Instance de Paris [High Court of Paris] upholds the claims made by a patient who has suffered injury due to a *colonoscopy*, resulting in the bowel perforation, risk over which he was not informed by the doctor, with the following reasoning: *choosing to minimize the concerned examination, the physician voluntarily prevented the patient to express his conscious consent to the existing risks.*

D. The duty to counsel the patient

While practicing his profession the physician has a moral and professional obligation to advise his patient in choosing the most effective treatment or intervention, providing information about the *prognosis of the disease without applying treatment, viable alternatives of the treatment, their risks and consequences*, according to Art. 649 para. (3) of Law no. 95/2006.

In this sense, we define the counseling duty as *the physician's duty to recommend his patient, based on information in its possession, of his scientific knowledge and professional expertise, the conduct the patient will have to adopt, the care and interventions needed for his healing or health improvement*. In other words, the purpose of patient information is a decision for which the specialist warning and recommendation is essential.

The counseling duty is distinguished by *the particular nature* of the physician's recommendations, on the one hand in relation to the patient's case and the right knowledge and professional experience of a specialist on the optimal medical solution to the problem, on the other hand. Although the opinion is to some extent subjective, it is based on the ensemble of information held by the creative improvement of the knowledge for choosing the optimal solution.

The legislator has included the counseling requirement in Chapter III, Title XV, respectively "*the patient's informed consent*", where we may conclude that there wouldn't be a distinct obligation, but information which requires the counseling of the patient.

In our legal doctrine we have studies enshrined regarding *the duty of information* in the field of pre-contracts with respect to the sales contract[29] and the *duty of counseling* [30] during the drafting of the contract.

The question of the physician's duty to counsel the patient "*regarding the treatment he considers most appropriate*" has been debated by Ionuț Florin Popa[31], within medical liability without being regarded as a distinct duty.

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[29] D. Chirică, *Obligația de informare şi efectele ei în perioada precontractuală a vânzării-cumpărării* [The obligation to inform and its consequences in the pre-contractual period of sale and purchase], R.D.C. no. 7-8/1999, p. 50 and ff.

[30] J. Goicovici, *Obligația de consiliere* [Duty of counseling], Dreptul afacerilor no. 4/2005, pp. 15-28. The author pleads for the consecration of the obligation of counseling, distinct from that of information, assessing that "*it is an obligation of guidance of the choice of the customer and even an obligation to dissuade thereof whenever concluding a contract in these terms would be dangerous, illegal, in contrast with the mandatory rules of law or of the professional ethics*". Among the exonerating cases of the debtor's liability are invoked: the buyer's lack of collaboration, ignoring the buyer's legitimate needs, his notorious competence, the assistance of the buyer by a professional counselor, contracting "*on the client's risk and danger*".

[31] I.F. Popa, *Răspunderea civilă medicală*, [Medical liability] Dreptul no. 1/2003, p. 50.

Moreover, the author Călina Jugastru[32] in the analysis of the repair of non-property damage, invoked the obligation *to inform and counsel,* summarizing their content in the contents of a single civil obligation incumbent on the physician, based on *the respect owed to the patient's life and personality*.

The French legal literature[33], addresses the question of advising and warning the patient in the broader context of the *duty of information*, particularly in contractual matters, including in the healthcare contract[34].

Liability for the breach of the physician's duty of counseling his patient may be invoked in the following assumptions:

- *the absence of any medical advice* is obviously a guilt of a physician who proves his lack of professionalism and total indifference to the patient's condition. If this circumstance is causally related to the harm of the disoriented patient regarding the way he would have chosen to follow, through the occurrence of complications or even death, we can appraise the counseling obligation as *an obligation of result* whose breach may result in the physician's civil liability of the doctor. The proof of fulfilling this duty falls on the physician, being permitted any evidence to prove this legal fact;

- *formulating a wrong opinion* which is the result of a professional misconduct, negligence or reckless imprudence or insufficient professional knowledge, will lead the physician's tort for the breach of duty of counseling, which is considered an obligation of result, along with those regarding the care and information for the patient.

In both cases, by the breach of this professional duty, the patient will be hindered to make a decision about the treatment or intervention that should do and which represents the lowest risk for his life and health.

In conclusion, we consider that there is a separate obligation of counseling by the physician to his patient previously, simultaneously and after the fulfillment of the medical act. The substantiation of liability is of *objective nature*, based on the idea of *the risk evolving from the exercise of medical profession*, as a consequence of the breach of an obligation "*of result*". We express our conviction that the text of the Law no. 95/2006, especially the provisions of Title XV, will

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[32] C. Jugastru, *Repararea prejudiciilor nepatrimoniale*, [Repairing the non-property damages], Lumina Lex Publishing House, Bucharest, 2001, p. 233.

[33] In this sense, see M. Farbre-Magnan, De l'obligation d'information dans les contrats. Essai d'une théorie LGDJ, Paris, 1992 and G. Viney, P. Jourdain, Les conditions de la responsabilité civile, 2006, n. 549.

[34] We note that in France, the Public Health Code adopted by Law no. 2002-3003 of 4 March 2002, has regulated legal framework of implementing a new position, that of *the mediator* in the medical field, a reliable person, who will assume a part of the patient's rights when he is unable to exercise them, such as those regarding the access to medical records, the right to information, the right to counseling. The patient attains the right to correct information and advice, with the respect of his privacy and confidentiality on medical information.

trigger debates among practitioners and theoreticians on the nature, content and implications of this obligation, intended to provide a meaningful interpretation required in dealing with cases where the physician's liability is invoked.

E. Duty of confidentiality and access to medical records

Medical secrecy, enshrined in the Hippocratic Oath, is absolute and general, being one of the oldest rules of the medical practice.

Article 642 para. (3) of Law no. 95/2006 establishes the civil liability of medical staff for damages arising from the breach of the duty of confidentiality. Medical units providing medical services, public or private, are liable for the damages caused to patients, arising from the failure of complying with the domestic regulations.

On the occasion of providing care and assistance, the doctor knows a lot of details from his patient's life, such as medical history, sensitivities, allergies, interventions etc. All these pieces of information are strictly confidential, their disclosure being prohibited without the express consent of the patient, as his personal life. The health institution can not publish the information from the patient's records, only at the request of authorities or courts, motivated by the pursuit of a legitimate interest. In case of death such information must be disclosed to family members at their request.

There are only three situations where the physician is obliged to inform the public on the state of the patient: his birth or death and in case of contacting a contagious disease that endangers public health.

Through these features, we can define the physician's obligation of confidentiality an obligation ancillary to that of care and medical assistance for the patient, which consists in keeping secret the information on the health status achieved during the patient's surveillance and in disclosing them only in exceptional cases, expressly provided by law.

We believe that the duty of confidentiality can be considered "of outcome" because the disclosure of medical information in cases other than those expressly provided by law, constitutes a clear result that undoubtedly demonstrates its violation by the physician. This means that the liability will be engaged on objective basis, independently from the culpability of the physician's conduct, on the idea of *risk regarding the practice of the profession in society*. The liability shall be removed only in case of force majeure or the victim's own fault, respectively of the patient.

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