THE RESPONSIBILITY OD THE HEALTHCARE WORKERS SHOWN THROUGH THE PRISM OF THE JUDICIAL PRACTISE

Biographic data on the author:
M-r Viktorija Badjakova
Doctoral candidate at the Faculty of Law "Justinian I"- University of Ss. "Cyril and Methodius"

Mentor: Borce Davitkovski PhD

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INTRODUCTION:

The medicine is an ancient science, a skill which is applied even BC. With the existence of the humanity there is a constant need of educated people who would help the ill and powerless. The same need rests upon a vast number of principles which dictate the directions of the adoption of complicated decisions referring to the fundamental rights of the ill and often the healthy people, i.e. their life or death. The legal acts from this area refer to the external control over the work of the healthcare workers in order to protect the rights and interests not only of the patients but of the entire society. Until the 20th century a very small amount of attention was given to the relationship between the patient and the doctor. From that aspect it can be said that the medicine had an over privileged treatment than the other professions which since their beginning were at the focus of the fierce criticism of the public. The sole control measuring the responsibility of the healthcare workers as a part of this profession was through the professional associations of doctors and medical workers which rested upon the medical ethics. However the rapid development of the medicine drew its future trajectory. The new ways of diagnosing and treatment of the illnesses and the newly developed viruses and influenzas increases and complicates the responsibility of the doctors. Therefore in some way a defensive medicine was created, or medicine which strives to protect and restrain itself from the responsibility through application of numerous and unnecessary/ uncertain examinations. All of this was and is accompanied by many suits for well based and baseless doctor mistakes and much more.[1] Precisely for these reasons a common standing was introduced among the scientists that the medicine needs special and enormous attention. But the intention of the legislation is not only to enforce penalties, but also to establish external control which is very important for the performance of the medical practice and simultaneously the responsibility thereof. +The legal regulations connected to the medicine are in almost every branch of the legislation: criminal, civil, administrative, social, obligational, and international and naturally in the highest legal act of the country- The Constitution[2]

The responsibility of the doctors is not simple at all because it implies treatment/ saving of the human life. The oldest preserved legal document referring to the doctor responsibility is the Hammurabi by-law dating from 2100BC.[3] This by law contained fee for certain surgeries and also there were penalties for damages such as sight loss or post- surgical death of the ill.[4] In Greece the members of the medical associations must give an oath before they start their career. This oath is popular until this day and is called Hippocratic Oath. In the Roman Empire the first by- laws incriminating the doctor responsibility are the Lex Cornelia and Lex Aquilia.[5] The middle ages are filled with Salem discussions about sorcery and magic referring to certain actions, medications and crops. In XII and XIII century in Italy during the ruling of Ruder the

[1] Gjurkova O. *Medicinska Etika,* University „ Goce Delcev“, Stip: 2011
[2]The same.
[3] Smith S. *The history and development of legal medicine.* Legal Medicine. Edited by Gradwoli RBH: St. Lous: 1954.
[4] For more information visit Babylonian Legacy: *http://www.crystalinks.com/babylonia.html* .
[5] Radišić J., *Medicinsko pravo* – Vtoro preraboteno i dopolneto izdanie, Belgrad 2008.

second and Fredrik the second the first legal provisions were adopted for state supervision over the work of the doctors. While in 1794 in Manchester Tomas Percival wrote the first "Code of ethical rules of the doctors". In the Republic of Macedonia the responsibility of the doctors is observed thorough many adopted legal acts, bylaws and codes of ethics. However the greatest judgment lies within the patients and the public. 100 successful diagnosis may be annulled with only one unintentional doctor mistake (which dies as a result of death or permanent damage of the patient) we are aware that in the last few years the patients have won many legal disputes which were well grounded or groundless. The doctors are constantly in the focus of the society and the media. The judicial practice is well developed in this filed which until 2 decade ago was only an unimaginative idea.

Case files from the practice of the German courts

1. Responsibility when leaving the bodies during surgery

Alien bodies (corpus alienum) is a death or reanimated matter which came into the organism in a non-physiological manner i.e. are artificially inserted. It can be matters deriving from certain parts if the same organism which behave as strange parts in the organism (bone parts for example)6

The manners in which the alien bodies may find their way into the human organism are different: through a mechanical injury, aspiration while eating, through doctor or dental interventions in the throat and the mouth of the patient as well as through surgery and injection. In this situation it is a matter of exclusively alien bodies which in the organism were brought through surgery or injection and stay in the organism unplanned and without the surgeon's knowledge. Those can be various tools that the surgeon uses. For example surgical threads, knives, tweezes, gauze, swabs, broken needles, sponges, derange kit, scissors, catheter parts act. In the literature there are cases when the place of the surgery is forgotten and appearance of non-surgical items like rings.

The forgetting of alien bodies at the place of surgery was a common occurrence in the surgical practice and some researchers gathered together 236 and 315 such case in their works. According to some estimations the unnoticed leaving of alien bodies at the place of operation is 1 in 1000 cases. Even the doctors are not immune to this phenomenon of forgetfulness. This topic was brought in the newspapers also, several years ago two drastic cases were particularly explained. The alien bodies were a bandage 30cm long and a gauze and swabs left in the same wound. In the first case the left alien bodies caused the death of the patient, while in the other two cases the alien bodies led to serious complications which lasted for several years until their presence was established and eliminated.

[6] Herring, J , ,, Medical Law and Ethics,, Oxford University Press, Oxford, 2006

Case file 1:

Causal state:

Announcing the death of the patient on 2. 4. 1983, the surgeon as a heeling device used a special drill bit. However, when he penetrated the bone of the patient the tip of the drill bit broke. The surgeon put the broken part of the drill bit into the bone where it was fractured, but the patient was not notified about that. In the surgery region the patient suffered certain postsurgical trauma for which the reason was not clear. The difficulties intensified over time, especially in august 1985. Therefore the patient the patient underwent another surgery in October 1985 in another clinic and there they discovered and removed the broken part of the drill bit.

Then the patient rose a claim against the doctor who made the first surgery and left the broken tip of the drill bit into the bone. Aside from claim the patient demands reimbursement for ill treatment. The court of first instance had the standing that the leaving of the broken drill bit tip into the bone does not mean that the respective doctor did not act properly, however the Court of First Instance decided that the concealing of this fact is a hidden mistake giving the plaintiff the right of reimbursement. Acting upon the audit, the Supreme Court in Stuttgart confirmed the verdict of the lower court.

From the adopted verdicts of the Supreme Court in Stuttgart**:**

The Supreme Court defends the standing that the defendant mustn't have kept silent the fact that the part of the drill bit remained into the bone, but is obliged to, in order to achieve proper treatment and to prevent the problems later on, notify the plaintiff for the remained alien body or to make sure that the patient is notified about that by the doctor who performed the later treatment. (So called therapist notification). The fact that the defendant was worried about the plaintiff only within the stationary treatment on 2.4.1983, and not during his postoperative treatment does not relief the defendant from that obligation. Moreover, the defendant was obliged to guarantee a therapist notification to the plaintiff at least by the doctor who treated him later on. He prevented such notification because the drill bit broke, a fact that he did not put into the surgery report.

According to the results of the proves in the primary procedure, the most significant fact is that the difficulties of the plaintiff staring from August until October 1985 have been provoked by the wrong treatment procedure by the defendant. In fact, when the doctor violates his/her duty when giving therapist notification to the patient, the patient should, in general, prove the relationship between the omitted therapist notification and their health damage, except when there is a big doctor's mistake. Big doctor's mistake is the bad action of the doctor which, from an unbiased doctor's point of view does not seem acceptable and responsible because such mistakes mustn't be allowed. In this case it is about a mistake in the sense of holding back the fact that the broken drill bit tip was left inside the bone which disabled the setting of the right diagnose of the later difficulties experienced by the plaintiff and the conduction of the proper medication. The exposure of the plaintiff to danger of permanent damaging of his health represents, according to the Supreme Court, a big mistake. Because the defendant committed a big mistake, he is burdened prove that the pain endured by the plaintiff form August until

October 1984 is not from the remained drill bit tip into the bone. However that prove did not help the defendant.[7]

2. Responsibility for the mistakes of the anesthesiologists

Anesthesia implies full numbness caused by suppression of the nervous system under anesthetics given to the patient so that the doctor can painlessly perform the surgery. The modern surgery cannot be imagined without anesthesia which is performed by a qualified doctor-anesthesiologist. There are two types of anesthesia in the practice- local or regional and full. Both of this kinds carry certain risks. Especially the full anesthesia which is the reason why the fear of anesthesia is bigger than the fear of the surgery. Still, the patients accept the risks of the anesthesia because they are predictable and can be avoided.

The local anesthesia also carries significant risks as it is the general opinion. It may provoke infections, nerve damage, abscess and even death. The local anesthesia may be lethal in case the anesthesiologist doesn't consider the patient's age and body structure while determining the patient's compatibility for the anesthesia, or doesn't study the used anesthetic enough or gives a wrong dosage.

The full anesthesia is, in itself, a heavy impact for the human body and is applied only in case of bigger and more complex surgeries. It carries a great amount of risk, but luckily the risks really realize.

During the post- anesthetic recovery the following complications may occur: respiratory and cardiovascular or renal complications, slow awakening, delirium, postsurgical pains, nausea, vomiting and hypertension. The most significant risk that the full anesthesia carries is the possibility of permanent brain damage caused by the lack of oxygen during the surgery and death. The death by anesthesia may occur in all types of surgeries and may be caused by all anesthetics and their combinations during the primary insertion of the anesthesia or it sustaining.8

It is said, in the professional literature, that the death caused by anesthesia is mostly a consequence of a mistake made by the surgeon and not a harmful reaction of the anesthetic. Luckily the death during anesthesia happens only once in 1700 to 2000 surgeries according to the experiences of the trained anesthesiologists. However this information cannot be fully trusted because it is valid for a certain amount of time and the pace of the sudden cases of death may be variable.

In the medical literature, the death during anesthesia is divided into several groups; 1) death which is not directly related to the anesthesia, but it is a consequence of the illness or the injuries provoking the surgery; 2) death which is a direct outcome of the applied anesthesia; 3) death which during the anesthesia occurred due to other medical causes; and 4) death caused by

[7] www.abanet.org

[8] Erwin Deutsch/ Andreas Spickoff, Medizinrecht 5 Auflage, Berlin, 2003

non- medical causes, for example, due to an explosion, fire or technical malfunction of the equipment. Regardless of the cause during the effect of the anesthesia or the surgery and is mostly described under the diagnose as Mors in tabula. The doctors usually say that the patient died due to "cessation of the heart work ".

However the death on the operating table is always suspicious, because the relatives of the deceased immediately start thinking that it is about some kind of doctor's mistake. To determine the cause of death the surgery report, the anesthesia report and the report for the patient's compatibility for surgery and anesthesia are of at most importance. It is not known how many patients die due to cessation of the heart work, behind which stands the mistake of the anesthesiologist or the patient's intolerance to certain anesthetics. However it should be considered that the damages caused by the narcosis are rarely a consequence of a predictable organic and physiological action, but an action parting from the rules of the natural sciences, thus from the legal observance.

Case files from the legal practice:

Real state of affairs:

The patient, eight years and nine months old, was directed to the hospital by his family doctor diagnosing him with "Acute inflammation of the appendix". During the hospitalization the patient was examined by the manager of the department of surgery Dr. W who noticed that the patient is a very tired and heavily ill child who according to the mother was vomiting the entire night, was very exhausted and had abdominal pains. Doctor W also diagnosed the patient with "Acute inflammation of the appendix". The urine and blood were not analyzed.

Due to the exhaustion of the child, doctor W ordered infusion with glucose for the child and then he called the anesthesiologist into the operating room and said that the child due to "Acute inflammation of the appendix" must be immediately operated. Also he asked the anesthesiologist to examine the child before the surgery in the children's department of the hospital. When the child was taken in the children's department, the nurse in that department noticed that the child does not have the look for his age, but looks as he was five years old. Because of the smell of acetone, her acetone tested a few drops of the child's urine and the results were positive three times but without sugar.

When the anesthesiologist came into the children's department the infusion with glucose has already started to enter the child's organism. The medical history form was on the table filled by the mother of the child. At the question for diabetes the answer was negative. The anesthesiologist examined the child superficially, harked the child's lungs and heart, he examined the throat, the tongue, the eyes and the mucus. During the examination of the throat he also smelled the acetone. Although he noticed that the child was apathetic and exhausted and very little weigh, determining that the child is rascally ill he did not perform further examination and sent the child to be operated. However the child did not awaken from the narcosis and died in a diabetic coma.

The anesthesiologist has been convicted with negligent homicide after the criminal procedure led against him.

From the court verdict explanation:

The court forensics concluded that the doctor even after he determined the smell of acetone and the symptoms indicating that the child was a high risk patient, was obliged to differentially examine the child's basic illness before the confirmation that the patient is able to endure full narcosis. The child's symptoms, especially the smell of acetone and the high exhaustion were spatially significant for the detection and clarification of the sugar concentration in the blood. However the smell of acetone may be present in other people who are hungry.

These two reasons for acetyl smell could be separated by determining the sugar concentration in the blood, i.e. by simple blood test. The infusion which contained sugar given by the doctor W prior to the surgery does not relief the defendant from his responsibility to determine the sugar concentration in the blood because he, as an anesthesiologist, should have examined the child's ability to endure the narcosis.

According to the opinion given by the court forensics as a reason for the death of the child the omissions of the defendant were stated as well as his decision to submit the child to narcosis where even during the narcosis application he did not supply the child with oxygen using a mask. More precisely, the application of the narcosis to the child who was in such a bad health state represents poisoning because along with the omitted oxygen supply this brought the child to an oxygen lack state which relating to the diabetic coma led to a further brain damage. Without this narcosis, the death provoked by the main illness (diabetic coma) wouldn't have taken place in the given moment.

In the case in question the defendant as an anesthesiologist was obliged to examine the ability of the child to endure narcosis. Because of that he was obliged, considering the explicit symptoms, to clarify the child's main illness. He could have done this by the simple blood testing method. He had enough time to do this because the child was diagnosed only with "Acute inflammation of the appendix" without perforation, so that the surgery did not need to be immediately performed.

The defendant could not refer to the so called thrust principle which is applied to the team thrust between the doctors belonging to different specialties. Furthermore doctor W called the defendant in person to examine the child in the children's department of the hospital. Therefore the defendant was not relieved from his duty to examine the child's ability to endure narcosis.

The death of the child, caused by the defendant, must be imputed to his negligence because it has been determined that he neglected his obligation for due diligence which regarding the circumstances and his personal knowledge and ability was available and could be shown, and he did not predict the consequence which he could have predicted had he done his due diligence.

The doctor who will take over the patient's treatment is obliged to do everything, according to the rules of the medical science and experience, which should be done in his situation to keep the patient alive and protect the patient from health damage. Thus it is the doctor's duty to act carefully and have high demands.

3. Case files and responsibilities for doctors' mistakes

The diagnosis is a short conclusion of the doctor for the basis of the illness and the state of the ill, with terms of the contemporary medical science.9 In most cases the diagnosis is not a purpose but it is in service of therapy determination. Without correct diagnosis there cannot be a correct treatment. However the purpose of the diagnose may be reduced to determination of the momentary health condition of a certain individual regardless of the therapy. It is done in case of expert evidence, determination of the working ability of a certain individual etc.

Prior to the diagnosis, the doctors must take various diagnostic measures such as examination and clinical examination of the patient. Aside from the physical examination of the patient, there is a number of other examinations such as the laboratory methods of examination, examination with certain devices such as x-ray and ultrasonic devices. The correct diagnosis may be set when the basic data of the patient are analyzed. Those data are sublimated in certain subjective difficulties (symptoms) and objective changes of the organism or clinical signs of the illness. The clinical picture is formed after the discovery of the symptoms and the signs of the illness. The problem is that different factors may cause same or similar clinical picture of a certain illness and often the symptoms and the signs of a same illness may be with a different intensity even when there is a same causal factor. Therefore it is necessary to follow the course of every illness in detail, sometimes hourly, daily or weekly to determine the correct diagnosis and treatment.

There are various types of diagnosis in the medical literature and that variety has certain practical values. For example: differential diagnosis, temporary diagnosis, causal diagnosis, revise diagnosis, pre -surgical diagnosis, prenatal diagnosis.

The terms diagnostic mistakes and wrong diagnosis are often used as synonyms. However it should be mentioned that they don't have to overlap unconditionally. For example it can be said that a patient may be unnecessarily exposed to certain devices in order to be diagnosed, but it does not have to result in wrong diagnosis. On the other hand the wrong use of the medical device (for example and x-ray) and inadequate diagnostic action (for example laparoscopy and endoscopy) may cause damage to the patient. The term wrong diagnosis refers to a strict intellectual omission (estimation), while the term "diagnostic mistake" covers irregularities in the area of the diagnostic examination. It can be said that the term diagnostic mistake has a wider scope because it is not restricted exclusively to the result, but covers the mistakes made on the road to the results.

The mistakes referring to the diagnosis may appear in 3 forms:

- As an incorrect or partial diagnosis;
- As an omitted diagnosis;
- As a late diagnosis.

[9] Gjorgji Martinovski " Etika vo sovremenata nauka „ University " Ss Cyril and Methodeus„ Skopje, 2007

The incorrect diagnosis covers three different segments: 1) wrong affiliation of a symptom to an illness to which the symptom does not belong 2) non recognition of the symptom thus making it impossible to discover the true illness and 3) wrong acceptance of certain symptom as part of the clinical picture of illness. In the practice the diagnostic mistakes are very common. The following examples are typical for that matter: thrombosis of the big abdominal veins, may be later diagnosed as a possible liver cancer, the headaches suffered by the girls are not a result of the former conception as diagnosed, but may be a result of brain tumor. The initial diagnosis – hemorrhoid hemorrhage later turns out to be rectal cancer.

Typical sources of a diagnostic mistake:

1.) Just like other professions, the medical practice, in the area of diagnosis, contains possible so called mistake sources. In this category belongs the following: the miss thrust, the vanity, the excessive pessimism or optimism, the possibility for constructive thinking, the lack of creativity for differential diagnosis, the intention to set an "interesting" diagnosis as well as incapability to enter the patient's reality, the patient's way of expression and to translate it in medical terms.[10]

2.) Most common source of diagnostic mistake which is relatively independent from the state of the medical science is incomplete medical history. Aside of that, the takeover of other doctor's diagnose is a risk characteristic for the division of work in the medical staff, especially when it is a word of multigradual diagnose setting. Therefore there are often mistakes during the examination of the laboratory data by the non- medical staff or displacement or interfusion of the laboratory findings due to irregularities of the technical devices or inadequate operation with them. As a factor for wrong diagnosis may be considered the doctor, or the doctor's insufficient knowledge.

4. Responsibility for diagnostic mistake

The wrong or incomplete diagnosis enables late diagnosis which can be corrected with the general legal regulations applying to the doctor's mistakes. It means that the diagnostic mistake is an objective term which does not contain an estimation for the doctor's mistake. That means that the doctor is not responsible for each mistake in the diagnosis, but only in case when the mistake was made on purpose or negligently. Besides, the doctors cannot be responsible for a wrong diagnosis unless it harms the patient. The damage is cause because the wrong diagnosis brings wrong therapy. Therefore a mistake in the therapy implies a mistake in the diagnosis because the wrong therapy relies on a diagnostic mistake.

On the other hand, if the diagnosis is late or has not been set at all, than the result may be the same as if it is the case of wrong diagnose, i.e. late treatment measures.

The mistakes in the diagnose are not always a consequence of a doctors' procedure due to which the doctor may be warned or responsible. Between the mistakes in the diagnose and the

[10] Kaličanin, P. (1999):*Medicinska etika i medicinsko pravo*, Institut za mentalno zdravlje, Beograd

doctor's lack of attention there is a big difference. The point, which the responsibility is mostly related to is not his wrong diagnosis, but the inattentive action of the doctor leading the situation to that result. It one thing for the doctor to make a mistake in his/ her judgment and it is another thing to make omissions while performing his/ her duty due to lack of attention. The professional irresponsibility of the doctor has its foundations exclusively on the negligence of the current medical standard. The doctor may be held responsible due to wrong diagnosis only in case the symptoms or the signs of the illness are clarified in a manner which is medically totally unacceptable, if he/she does not supply the basic control findings or of the temporary diagnosis is not consulted during the further treatment or examination of the patient, especially because the treatment does not give any results. The lack of affiliation with the illness or the symptoms is always justified by guilt.

The danger may be applied to the diagnostic mistake in the following cases: the doctor can lie about the evidence gathering on the site, while transporting the injured patient in a traffic evident and those evidence are important for the further treatment and therapy, the doctor who ignoring the basic medical knowledge prescribes to the patient a pain killer for the abdominal pains without clarifying the consequence thereto; the doctor who suspect that it is a case of a very had illness but does undertake further diagnostic measures and correct treatment, the doctor who does not perform histological examination for tumors due to the suspicions abstained from the basic examination on the x- ray device.

It can be concluded that the court practice is more valid in the acceptance of the diagnostic doctors' mistake then in the acceptance of the mistake made in the therapeutic area of the medicine. The claims for reimbursement of damages due to mistake in the diagnosis are often denied with the explanation that considering the difficulty of the diagnose setting there is no mistake for which the doctor may be warned to that it is a mistake which should be further determinate or it is a very small mistake. The liability to make reimbursement for the mistake is present when it is acai OD fundamental mistakes in the diagnosis. In addition, there is a difference made between the diagnosis as an explanation of the findings, as an estimation or conclusion of the diligence or the diagnostic measures previously estimated. The estimation is not made equal and turned into a general code of conduct the violation of which would mean guilt. The diagnostic measures which previously set the diagnose and the results of which serve as a foundation for diagnose setting, are submitted to certain medical standards (diagnostic standards). That, in the practice, results in the common responsibility of the doctors due to omission made in the diagnostic measures, as well as a mistake in the estimation of the illness. It is very similar with the court verdict brought without fully state of the facts due to which there is a mistake of the legal qualification of the case resulting in wrong verdict.

Cases form the court practice:

Case file 1:

State of the facts

On 14.01.1981 in the hospital K a caesarian section due to childbirth has been made on the patient K. Few days later the woman says that she has pains in the left hip which reflect on

the leg. The gynecological examination of the woman did not show any certifiable result. For that reason the manager of the gynecology department of the hospital called a surgeon for help, doctor A. The surgeon examined the woman on 22.01.1981г. And in that situation she once again said that she has pains in the area of the hip ankle. Doctor A ordered an x-ray of the hip, but the x-ray picture was also unclear. Then doctor A prescribed a pain killer to the woman. The pains were not mitigated to a great extent and her body temperature rose and the woman stated taking the antibiotic amaxipen 3 times a day, as ordered by doctor A. On 01.02.1981 the patient had her head examined due to her release and in that situation she did not say she had pains. The next day (02.02.1981) she has been released form the hospital. The doctor letter sent to her family doctor contained the following " On 02.02.1981 we released Mrs. K because she felt better and did not say she had any pains and the further caretaking is reffered to her family doctor "

However the patient had further pains in the area around the hip. For that reason she was referred at the orthopedic department in another hospital by her family doctor on 17.02.1981. There on 20.02.1981 upon the x-ray examination she was diagnosed with festering inflammation of the hip ankle (coxitis) in a further state of development due to which the curtilage filming of the hip and hip ankle was fully deteriorated. Then an operative revision of the left hip ankle has been made. However due to the length of the slow initial diagnosis there has been a difficulty in the patient's movement, with hip stiffness and reduced leg movement. Due to incapability to work she has been fired from her work post on 17.06.1981.

The patient rose a claim against the hospital K and the gynecology department manager. Along with the claim she demanded a tangible and non- tangible reimbursement for the stiffened hip. The court of first instance approved a tangible reimbursement due to the monthly loss of financial gaining and a decision for rent amounting 1.409,75 dm and non- tangible reimbursement amounting 20.000 dm. Upon the appeal submitted by the defendants the Supreme Court altered the verdict of the court of first instance and denied the claim, the BundesCourt of Germany removed the verdict of the court of appeal of the Republic of Germany and returned the case into a second trial.

Supreme Court decision explanation:

Opposed to the court of first instance, there is a suspicion that the plaintiff's pains during her stay in the hospital K are symptoms for coxitis in an initial stage of development, but that matter is highly uncertain as well as the matter of the other accused gynecologist and surgeon doctor A, who has been called as a conciliar doctor and can be held responsible for the wrongful action during pain diagnosing. This court did not accept that doctors have made a big mistake in the treatment and there has not been fundamental damage in the diagnosis, because the forensic-professor R did not mark the omission in the diagnostic measure as fully baseless. According to that the court considers that the plaintiff must prove that further along the correct diagnose "festering coxitis could have been set with additional medical examination in order to reach the desired treatment with no complications and permanent damages. She did not provide that proof.

Verdict explanation of the Supreme BundesCourt:

The Supreme BundesCourt considers that the Supreme Court had misunderstood the allegations for proof factors beliefs in the case of the big doctors' mistakes especially because of the omissions of the important necessary findings and that is why the state is insufficiently. It obviously missed them in benefit of the plaintiff, that the doctors from the hospital K made a mistake in the treatment because the pains I the hip noticed by the plaintiff are not sufficiently clear. Because of that the therapy was begun after the surgery, prescription of painkillers and antibiotics on a based suspicion for lumbago was insufficient and ineffective.

The revision with the right of advice from the forensic professor R made on the medical treatment of the pains in the area of the hip noticed by the plaintiff is marked as insufficient and wrong. According to his opinion a further diagnostic solution of difficulties is necessary because the first clinical examination and x-ray examination did not give any results. The forensic taught that at least he should perform a small laboratory examination, than an x-ray in layers or a referral to the patient to an orthopedic or surgical clinic. Aside of that the forensic considers that from the beginning the doctors should have taught of the inflammatory process in the hip area where the patient felt the pain because the inflammation appeared during her stay at the hospital after the surgery known to the doctors.

Opposed to the view of the Supreme Court the BundesCourt accepts the big mistakes in the treatment which lead towards displacement of the proof of the factors from the plaintiff to the defendants. More precisely, the beginning should be from the fact that plaintiff claims that with the further medical examination the correct diagnose could have been set and on the basis of the correct diagnosis a correct treatment would have followed and the process would have ended with no complications and permanent damage.

On the other hand the BundesCourt has a firm standing that the objection of the plaintiff against the doctors in the hospital K is not basically directed toward the fact that they made a big mistake in the diagnosis. It is about whether the doctor has omitted to gather the usual findings to clarify the suspicions about the diagnosis which based on the circumstances had to be imposed and whether with the wrong use of medicaments the picture of the illness was distorted. In the opposite case, on the first place there is no wrong perception of the findings, but lack of findings and instruction of a wrong therapy. Opposed to the understanding of the Court of Appeal it should be considered, beside all the medical experiences, the inflammation as a factor for the appearance of the pains at the plaintiff. From the explanations of the forensic it can be concluded that it applies, although in the medical literature the possibility for coxitis after a caesarian section is not described, because after any surgery in hospital there is a possibility of bacteriological infections that must be taught of.

The question of whether the mistake in the treatment may be treated as a big mistake is a question of a legal estimation and should be answered by the court and not the forensic. The responsibility of the secondary accused doctor is not any less because he has been called as a conciliar expert to help the surgeon A. At the same time the secondary accused worked as a gynecologist- surgeon must have had responsibility for the medical knowledge and must know

the right procedure in case of postsurgical complications. The council does not relief him form responsibility.

5. Responsibility due to the damages provoked by the use of the medical devices

It is known that the medicine massively uses various types of instruments and their usage grows each year. The instruments directly enable the diagnose and the therapy and the modern medicine cannot be imagined without them. Besides the regular handy instruments with the help of which the daily medical routines are performed, there are the combined instruments which in scent a certain force and serve to perform complicated medical procedures. For example: x-ray devices, thermotherapy devices, dyalisators, narcosis devices, defibrillators high frequency surgery devices etc. Many surgical procedures on the patients and the so called intense medical care are possible thanks exclusively to them. However there are medical instruments which do not serve for the patients' examinations or treatment, but are used in a different manner (for example hospital wheelchair, beds etc.).

The massive use of the existing techniques has led to depersonalized medicine, to alteration of the relationships between the doctor and the patient. Because the patient trusted only to his/ her doctor and now thrusts mostly to the medical devices. However the use of the instruments in the medicine is not fully safe or harmless. The instruments may sometimes stop working and give wrong data for the health state of the patient or to bring danger to the patients' health or live. The instruments can stop working if they have been wrongly operated by the doctor or his/ her assistant or due to wrong functioning of the instrument. It excludes the responsibility due to danger protection. In other words, the doctors and the health care institutions which use medical instruments are obliged to respect the current medical- technical standards and to obey the safety regulations.

6. Special legal liabilities of the operator of the medical devices

In order to warn about the danger of the damages provoked by the use of the medical devices, their operators are burdened with the following legal liabilities: to use the most modern instruments, to familiarize with the functioning manner of the instrument and to maintain the instruments regularly and to control their performance.

The obligation to use the most modern instruments

The doctors and the healthcare institutions must have and use medical instruments which they need for their job. The performance of the medical activities with no instruments suitable for that purpose is a doctors' mistake which can burden the doctor with responsibility for the patient: "the healthcare institution which does not contain the technical conditions to undertake

surgical interventions with special warranties and takes them over and is responsible for the damage".[11]

It is considered that the doctor makes a big mistake if the existing medical therapy instrument is not used although its use has been identified.

In the legal literature and the court practice the view that the patient may ask the doctor to treat him/her with the newest medical devices has been accepted. However this view does not apply indefinitely because carte must be taken for the economic possibilities of the doctor and the healthcare institution. It cannot be expected that each doctor and each healthcare institution to possess the newest medical instruments,12 and naturally the most expensive ones. It is enough if the instruments at disposal, even though not the newest ones, to di their purpose and to be adequate to the medical standard. So the state constitutional court in Frankfurt for one case decided the following: "The use of old surgical instruments for polyp removing from the wall of the colon shall be allowed unless it is technically unequal with the modern instrument". When the obsolete instrument is no longer suitable for the medical standard, the doctor who cannot or does not want to supply the newest model should direct the patients toward his/ her colleagues i.e. towards some healthcare institution disposing with that instrument. In Germany there is a law which prescribes the time during which the big medical devices may be used in the benefit of the patients who have health insurance.

Obligation to familiarize with the manner of instrument functioning

The persons using medical instrument are obliged to previously familiarize themselves with the instrument functioning and to be trained to operate it. The inadequate operation with the instrument which would be harmful for the patient may be characterized as a doctors' mistake and implies responsibility. Such is the case when the doctor operating the –ray device is not familiarized with the operating manner of the new apparatus for thermotherapy and uses high voltage current due to which the patient suffers burning. The needs of the court practice demand attention from the doctor but not to turn into a technician in a white coat. More precisely, the doctor is not asked to be familiarized with the operating manner of all medical instruments in detail. However that does not relive him/her form the obligation to familiarize him/herself with the functioning manner of the instrument especially when the instruments have a vital meaning to the patient.[13]

The danger from complications, imperil and damage emerging from the use of the medical techniques provokes cooperation between the producers and the users. Besides that most of the healthcare institutions should employ specially trained technicians handling the complex medical devices. That is why the legal prescription in certain countries notifies the doctors and

[11] Decision of the Supreme Court of Slovenia 1968. Published in : Collection of Court Decisions, decision no 464

[12] Verdict from 21. 09. 1989, stated in Laufs/ Unlebuch

[13] Spickhoff A. *Medizinrecht,* 5 Auflage, Berlin: 2003.

the healthcare institutions to give the responsibility of handling the devices endangering human life with their operation exclusively to specially trained people to operate them thus avoiding the possible danger.

The responsibility for instrument control and maintenance

Regarding the responsibility for the medical instruments' maintenance it is enough if the doctors or the healthcare institutions respect the directions given by the producer or contact the produce maintenance service. That ensures the correct functioning of the device. However the functional capability of the instruments may be controlled by the doctor while using them. For example some of the foreign courts assume that prior to each surgical routine requiring narcosis it is necessary to optically examine the intubation system. The doctor does not have to examine all instruments him/herself provided that there is trained staff helping him/her. However the doctor is required to be familiarized with the manner of operation of the instrument and the possible obstacles which may bring the patient in danger. The doctor responsible for the use of the medical instruments should know when it is necessary to call a trained expert for help. Because the doctor and the healthcare institution are held responsible if it is determined that the damage of the patient has been provoked by the insufficient technical application.

The doctor mustn't blindly believe in the well-functioning of the technology and must control it during the use. The doctor is expected to monitor the not only the instrument in use but also the patient's reaction who may complain that the instrument is malfunctioning. It applies especially for the medical devices having self-operating mechanism attached to them which the doctor mustn't blindly believe in and forget the responsibility he/she carries toward the patient. In that sense the Supreme BundesCourt of Germany adopted a very wise verdict. It has been decided that anesthesiologist should be held responsible because he/she did not detect the signs of skin darkening the patient exhibited provoked by lack of oxygen (cyanosis), after which the control instrument was exclusively implemented which gave wrong information that the oxygen supply is enough. Had the anesthesiologist detected the patient's reactions he/she could have timely conclude that the narcosis device is malfunctioning and save the patient's life.

7. Ground for responsibility due to damage provoked by the medical device

Responsibility based on guilt

The legal prescriptions in the functioning of the medical instruments are mostly reduced to their installation, negligent maintenance or irregular handling. Those are reasons for which the human factor is responsible and which may be excluded with careful operation and help organizing the work. If the patient's damage is conditioned by any of the aforementioned, it is an indication that some of the medical workers or technicians violated their duty to act diligently. In such cases the guilt as a responsibility ground is sufficient to cover the accidental mistakes. In other words the damage responsibility provoked by the medical device may be separated according to the general rules applying for the medical staff.

Responsibility in case of unexpected failure of the instrument
the medical instrument may suddenly fail and provoke damage of the patient's health or death

and the person handling the instrument or monitors the situation cannot be held responsible. Therefrom, in the legal theory and practice the following question is asked: Who should carry the risk from unexpected or unavoidable failures of the medical instruments- the doctor, the healthcare institutions or the patient? The courts in some countries consider that the damage form the medical devices is not reduced to an irregular action of the medical staff, but the patients Carrie them themselves. The aforementioned courts do not retreat from the regular responsibilities on the ground of guilt. It is not decided that the risk from medical device failure is the doctors' fault because of the fear that the medical devices will cease to be used. That in the end would be harmful to the patient because he/she would not obtain modern diagnosis and therapy. To avoid that danger the problem is estimated according to the "cost - benefit" principle. If the patient wants to be treated with modern medicine, he/he must accept the immediate risk and the consequences thereto.

This view has been expressed in a verdict adopted by the former Federal Court of the Socialist Federal Republic of Yugoslavia. In the verdict it has been stressed that the "hospital is a holder of harmful substances is causally responsible for the damage which shall follow and is endured by the hospital worker or a third party, unless the harmful substances are used for the treatment of those persons". It was a case when the plaintiff demanded a damage reimbursement due to the surgery of the yolk sac when the hemorrhage has been stopped by thermocautery. Then a short circuit occurred in the cable between the device and electrodes located on the shinbones of the patient and the patient got burned. The low instance courts taught that the thermocautery is a dangerous device and that its application represents a danger for which the hospital should be held responsible by the "Expression principle" according to Articles 173 and 174 from the Obligation Law. However the Supreme Court of Croatia did not accept that view and annulled both verdicts adopted by both courts. In the explanation of its verdicts the Supreme Court states that the hospital which is the holder of the device as a harmful device shall be responsible according to the "Expression principle" only for the damage following its harmful characteristics endured by the worker in the hospital or a third party. The persons for the treatment of which a harmful substance is used by the hospital, the hospital shall be held responsible only in case there is guilt carried by some of its employees, i.e. if they omitted to examine the correct functioning of the device or if the device is not operated properly.[14]

However the Supreme Courts of the Republic of Bosnia and Herzegovina in a later decision had the opposite standing, i.e. to hold the institution responsible according to the principle of objective responsibility only in case there is a damage endured by the patient provoked by the malfunction of the medical device even when the malfunction of the medical device is provoked by construction mistake of the producer.

The German courts facilitate the state of the damaged patient in a manner that the they do not apply the valid rule for the burden for guilt proof. They do not ask the patient to prove

1) [14] Decision of the Supreme Court of Bosnia and Herzegovina no. 102/ 85, from 11. 06 1985, Collection of Court Decisions, books 10, world 1 – 2 / 1985, page 183

negligence from the doctor or his/ her assistant while handling the medical device. Moreover the courts draw the conclusion from the malfunctioning that there is guilt for the person handling them. In order to relief from responsibility, the doctor and the healthcare institution should prove that they acted quickly and that the machine failure was unavoidable. Such counter proof is possible only in rear cases because the person handling the machine is expected to be careful regardless of the circumstances. With that the responsibility is not accepted regardless of the guilt applying for so called harmful substances and dangerous actions, but a step in that direction has been made. The general legal prescriptions and the legal theory of Austria, Netherland and Switzerland allow the possibility, for the damage of the patient conditioned by the medical devices, to apply rules for objective responsibility. However that that opportunity has not been confirmed by the authorized court practice. The situation is somewhat similar in France also. The responsibility for damage from the medical devices, the French courts resolve mostly within the Contract Law. In case of medical device use, it is considered that there is an obligatory result which guarantees full adequacy in the manner the device is used, so as a lack showing that the responsibility of the user may be exempt only in case it is proven that the damage has been done by somebody else. Special responsibility for cases upon Article 1384 from the French Civil Code playing relatively small role because the doctors and the healthcare institutions respond mostly to the contract with the patient. It is the same situation with the Belgium Law.

Responsibility of the producer of the medical instruments

The medical instruments may fail as a result form its faults existing from the moment he producer put them in circulation. Such cases should consider the responsibility of the producer for the relationship between the faulty product and the damages suffered. The producer cannot be relieved from the responsibility if proven that some of the conditions determined with Article 8 from the law exists. However in some countries the healthcare institution and the producer of such medical devices are held responsible solidary before the patient. Such is the case in Germany and the USA.[15]

The responsibility of the producer of the medical instruments is not in situation to cover the risks form the damage conditioned by the faulty functioning. Therefore it is good to consider the objective reality of the doctor and the healthcare institution using the medical instruments. Starting from this, when it is about their malfunction, it is not the risk deriving from the patient, but form the technical devices.

8. Court practice in the Republic of Macedonia

The Health law covering the protection of the patients from possible doctors' mistakes as commonly known, is present in the Republic of Macedonia and is operated by many law firms. According to the alterations in the legal legislation, prior to the submission of a civil claim for reimbursement of tangible and nontangible damage a forensic expertise should be performed.
Here it is about several medical expertness. One is about determination of possible omissions or miss actions according to the doctors' doctrine and opposes to the rules of the profession of the doctors for authorized court forensics from the same profession who would determine that in the

[15] *Standards of Ethical Conduct for Employees of the Executive Branch,* Washington DC: 2002

concrete situation the doctor and the doctor team did not take all the measures at their disposal according to the rules of the profession thus endangering someone's health, life or life functions. That is one thing. After that a neuropsychiatric expertise is made to measure the degree, type and the intensity of the psychological pain as ground for reimbursement of nontangible damage. Regarding the court treatment of the doctors' mistake there is a distinction in the criminal and the civil procedure because in the criminal procedure the guilt of the perpetrator is determined which occurred due to negligent treatment of the ill or due to criminal acts against the life and health of the patients, while in the civil procedure it is determined whether the certain claim for reimbursement of tangible damage or nontangible damage is founded.

„However in the Law on Civil Procedure it is envisaged that when the court decision depends on a prior issue, as in the case of existence or absence of a criminal act and criminal responsibility according to Article 201 paragraph 1 indent 1 from the Law on Civil Procedure the court shall terminate the civil procedure until the legal ending of the criminal procedure during which the guilt of the perpetrator of the criminal act should be determined and we know that the guilt is the basis for the responsibility of the provoker of some damage, additionally according to the Criminal Code the intention is not envisaged while perpetration of such type of criminal acts perpetrated by the doctor, but that the legal legislation in the Republic of Macedonia exclusively envisages that these criminal acts are perpetrated due to negligence. The amount of the reimbursement depends on each case individually and on its kind and degree and the character of the bodily damage or life endangerment, also from the possibility of their further removal or facing the patient with the permanent damages.[16]

Conclusion:

Defense -attack; attack- defense is necessary when it is a matter of sports or sadly battlefield. At the attack as a claim by a damaged patient wanting to protect his/ her basic human rights and the counter defense of the doctor/ healthcare institution for proving the opposite, i.e. that it is not a matter of a doctors' mistake is a long and above all agonizing process. Of course there is only one satisfied party. The motto of each human and honorable doctor should be to care only for the wellbeing of the patient and there is no other way. The thrust given by the patient with the sole selection of the doctor should be a motivation for the doctor to justify such selection. However the responsibility/ doctors' mistake/ wrong diagnosis is above all responsibility for the healthcare worker/ institution but a big part for its occurrence or absence is held by the state. The introduction of effectiveness as well as the implementation of my time in the healthcare system in the Republic of Macedonia, in no case shall provoke decrease of the doctors' mistakes, but the opposite. The tension to examine the patient in a timely manner as the obligation to take as many patients and examinations as possible which in some cases are unnecessary is not useful for the doctors. But the patients are the above all the damaged party. The percent calculated salary enables the increment of the negligent behavior of the doctors. Because, with the new reform system, the doctors see their patients only as numbers. Therefore we are witnesses of many court cases occurring into our legal system. In order for the court

[16] www.akademik.com.mk

proceedings to end well in the future it would be useful if there were more specialized attorneys/ specialized experts in the field of the medical and legal matter. The idea of establishment of a Healthcare Court dating form 17 century is not naïve at all. The concretization and systematization of a court whose single duty would be the resolution of medical issues is not useful at all, on the contrary. But to reach that objective there should be a well prepared terrain for that idea to be able to function. The Court of Honor within the doctor chamber would be good to be consulted frequently for advice and to be a part of such case solution. Since we already have such court it would be logic to respect it and use it in order to achieve just full verdict of some case. The introduction and implementation of contemporary devices is most certainly a positive critique, but is it enough to only be implemented. In order to have successful application of the devices the healthcare workers should be trained and educated. The first application of the device setting should not be applied primary on the patients because they are not lab rats, the primary application should be on phantoms. The surgery recording is a good method where the surgeon may really observe the performed task and the mistake made, but the recording cannot be performed as was the case when the Helsinki Committee rightfully rose, without knowledge of the patient- a minor in this case. At the end, of course, where there is a mistake, there is a base for CLAIM because according to an old saying the customer, in this case the patient is always right when an unwanted complication is made to them or when they are damaged.

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