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ОРИГИНАЛНИ НАУЧНИ РАД

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OBJECTIVE LIABILITY FOR DAMAGES IN MEDICINE AND PREVENTION OF VIOLATION OF HEALTHCARE RULES (MEDICAL ERRORS)**

Abstract: *In legal theory and jurisprudence in the Republic of Croatia, the prevailing view is that compensation for damage in healthcare should be judged according to the principle of guilt. In relation to damage caused by dangerous goods or hazardous activities in medicine, the most prominent tendency is the application of objective liability for damage. In this respect, the decision of the Constitutional Court of the Republic of Croatia is of particular importance, as the basis for changing the practice of regular courts when it comes to liability for damage caused to a patient due to dangerous goods or hazardous activity. The model which is applied around the world, primarily in the Scandinavian countries, New Zealand and the United States, is the principle of compensating the damage sustained by the patient, the so-called “no fault-no guilt” model or “no fault compensation scheme” (compensatory pattern without guilt). This model entails administrative and not civil procedure. In all no-fault systems, medical errors need to be registered in order to avoid similar situations in the future. These models provide for high transparency of the healthcare system and they aim to provide quick and just financial compensation without long-standing court proceedings and high costs.*

Keywords: *Damages, medicine, liability for damage, medical error, no-fault.*

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1. Introduction

The general rules on liability for damage under the provisions of the Obligation Relations Act apply to damage incurred to a patient during the provision of health services (Klarić, 2004: 112).¹ Regarding the rules on liability for damage, we differentiate between the types of liability for damage that come into consideration for the application of damages in medicine. Thus, we can talk about the rules of contractual and extra-contractual liability, subjective and objective liability, as well as responsibility for another (Klarić, 2004: 113). Each type of liability for damage has its own special assumptions and its scope of application. When the damage arises, the first question is according to which rules on liability for damage it will be judged (Klarić and Vedriš, 2006: 604). In the Republic of Croatia, the prevalent view in legal theory and jurisprudence is that liability for damage in healthcare should be judged on the basis of the principle of quilt (Crnić, 2008: 135).

2. Features of the Liability for Damage System

2.1. The Subjective Liability System

The importance of choice between subjective or objective liability is expressed as to whether, besides unlawfulness, in an objective sense, as a prerequisite of responsibility, guilt should also be claimed as a subjective element of unlawfulness (Klarić, 2003: 390). In the Croatian legal system, as a rule, the offender's subjective liability is presupposed. In that case, the injured party must prove the harmful act, damage, and the causal link, while the offender's quilt is presupposed. However, the lowest degree of guilt is presupposed, which is a common negligence. Any higher degree of guilt, such as intention and extreme negligence, must be proven by the injured party (Klarić and Vedriš, 2006: 610). Furthermore, the ORA² stipulates that a participant in obligation relations is obliged to fulfil the obligations relation to his/her professional activity with increased care in accordance with the professional rules and practice (to exercise due care of a good expert) (Crnić, 2006: 8). Therefore, for healthcare professionals, this provision establishes that a standard of their professional care is determined on the basis of two criteria: according to persons in their professional circle, and the specific circumstances of medical intervention (Klarić, 2003: 401). In this regard, it is necessary to take as a criterion the duty of care of an experienced and competent healthcare professional of the same category and rank as the

1 Obligation Relations Act, *Official Gazette*, no.35/05, 41/08, 125/11, 78/15, hereinafter referred to as the ORA.

2 Art. 10. para. 2. ORA.

one whose behaviour is being evaluated: a general practitioner, a specialist (Klarić, 2003: 401).

Subjective liability for damage, especially in the area of liability for damage in medicine, may also be subject to certain objections. Thus, it is emphasized that in case of subjective responsibility, physician's guilt has to be proven. The patient's position is particularly difficult since, as a non-expert, a patient has to prove the violation of the rules of highly specialized activity and the existence of a causal link³ between a medical error⁴ and sustained damage. This is particularly problematic given the fact that experts in these cases are physicians whose impartiality can for obvious reasons be questioned (Klarić, 2003: 392). The subjective liability for damage system does not show signs of a reduction in the number of court proceedings resulting from medical errors. On the contrary, the number of proceedings before the courts is steadily increasing, entailing an increase in health care costs (Kessler, 2004: 3).

2.2. The Objective Liability System

Because of the aforementioned, there is a growing tendency to introduce a system of objective liability for damage in medicine. In the system of objective or causal liability, guilt of the offender is not required for damage liability to occur. Hence, the liability for damage arises when the following assumptions are fulfilled: harmful action, damage, illegality of harmful actions, and a causal link between the harmful actions and the incurred damage. However, in case of damage caused by dangerous objects or hazardous activity, the injured party does not need to prove the causal link, which is presupposed (Klarić, 2006: 613). It is precisely with regard to damage caused by hazardous goods or activities in medicine where we see the most intense tendencies for the application of objective liability for damage. This is based on the reasons for the increasingly frequent use of certain devices and the introduction of technology in medicine that did not exist until recently (laser, robotic surgery, radiation, etc.). In this

3 Causal link or *causal nexus* is a connection that must exist between harmful actions and damage, indicating that the damage occurred as a result of a harmful action. In the nature of things, damage is the result of a multitude of causes. From this multitude, one has to be chosen as legally decisive. In this respect, the position on adequacy causality is applied in the Republic of Croatia, i.e., from many circumstances surrounding the damage, the cause is considered to be only the consequence which in the ordinary course of things (which is common in life) leads to such consequences. The injured party must prove the existence of such a causal link (Crnić, 2006: 705).

4 Different terms are used in medical and legal terminology: medical error, expert error, adverse event. The term *medical error* was determined by pathologist Rudolf Virchow as a "violation of general rules of treatment because of lack of attention or caution" (Klarić, 2008: 31).

respect, even in countries that apply the rules of subjective liability, there is more frequent insistence on the introduction of objective liability for damage caused by medical devices (Klarić, 2003: 395).⁵ However, in the Republic of Croatia, court practice consistently applies a system of subjective liability to damage incurred in medicine. The legal basis for the application of objective liability for damage to a physician is contained in the ORA, on the basis of which damage caused by goods or actions which have a higher level of inherent danger for the environment are subject to liability regardless of guilt.⁶ Thus, in Croatian claims law there is a legal basis for the application of objective liability. It is necessary for the court to determine in each individual case whether a particular good or action which entails an increased risk of damage to the environment was the cause of the particular damage. In that case, the court must apply the rules of objective liability (Klarić, 2004: 119).⁷ The court cannot ascertain that damage stems from a dangerous object or action and determine damage according to the rules on subjective liability (Klarić, 2003: 395). Our case law considers that medical treatments involving the use of procedures that by their very nature constitute a dangerous good or action have a certain risk for the patient's health, but if such a medical risk is accepted as usual, regardless of the possibility of occurrence of damage, healthcare professionals and institutions are liable on the basis of the principles of subjective responsibility. It is considered that the patient himself/herself bears the risk of damage resulting from the use of dangerous objects if the rules of the medical profession require the use of that dangerous object to eliminate the risk of the disease (Jelčić, 2007: 23).

2.3. Review of the Existing Solutions

Legal considerations on the recognition of patients' right to compensation for damage by applying the principle of objective liability are beginning to appear in our legal theory and jurisprudence. Thus, it is emphasized that medical devices are the basic means used by hospitals in performing their medical activities and generating revenues. A position arguing for the application of objective liability is that it is fair that the one who benefits from performing a particular activity

5 About the reasons and benefits of the system of objective liability, for more information see *infra*.

6 Art. 1045. para. 3. ORA.

7 Judicial practice and legal theory determine the concept of hazardous goods as those which by their intended use, characteristics, position, location and mode of use, or otherwise constitute an increased risk of harm to the environment; therefore, they should be monitored with increased attention. Dangerous activity is an activity which in its normal course, due to its technical nature and mode of operation itself, can endanger lives and health of people or property; therefore, such threatment requires increased attention of the persons performing the activity as well as the persons who come into contact with it. (Klarić, 2006: 615).

which, due to its dangers carries an increased risk of harm to other persons, compensates for damage caused by that activity (Klarić, 2003: 394). There is also an opinion that, when determining liability, it is important to determine whether the incurred consequences are common with regard to the type of medical intervention and methods. If these consequences exceed the normal risk limit, there is objective liability (Jelčić, 2007: 24).

In this respect, the decisions of the Constitutional Court of the Republic of Croatia U-III-1062/2005 of 15 November 2007 is of particular importance. In the aforementioned decision, the Constitutional Court confirmed the view of the municipal and the county court that the apparatus for conducting physical therapy with galvanic current by its properties, purpose and position is a dangerous object, and that the therapeutic procedure of using galvanic current is a dangerous activity; therefore, the person performing that activity is liable for damage sustained from that activity (Constitutional Court U-III-1062/2005). The municipal and the county court obliged the sued hospital to compensate the patient for damage (third degree burns) sustained during the galvanic current therapy. The courts referred to Article 174 paragraph 1 of the Obligation Relations Act⁸, which corresponds to the ORA provision that stipulates that the owner of a dangerous object shall be liable for damage resulting from the dangerous object and the person involved in the dangerous activity shall be liable for damage resulting thereof.⁹ This decision of the Constitutional Court of the Republic of Croatia is the basis for changing the court practice of regular courts when it comes to liability for damage caused to a patient by a dangerous object or a dangerous activity (Jelčić, 2007: 25).

3. Tendencies and Reasons for Application of Objective Liability for Damage

More recently, there is a tendency, even in countries that consistently apply the rules of subjective liability for damage to medicine, for accepting objective liability for damage, and not just for damage caused by medical devices (Klarić, 2008: 45).

The human factor can be attributed to 60-80% of all medical errors, which are relatively common. The fact is that medical errors have not been registered for years. In recent years, medical errors have become a topic more openly discussed (Ćepulić, 2008: 112), and there has been extraordinary expansion of court procedures based on medical errors. On the other hand, certain medical

8 Obligation Relations Act (ORA), *Official Gazette* no.53/91, 73/91, 111/93, 3/94, 7/96, 91/96, 112/99 and 88/01.

9 Ar. 1063 and 1064 ORA.

studies conducted at Harvard indicate that most of the 30,000 hospitalization cases that resulted in lawsuits did not include a mistake by a physician. However, it is emphasized that even if physicians won the lawsuit, it was a losing position. At best, they were presented as unprofessional (Bernstein, 2013: 715). For this reason, a new principle for compensating patients was introduced around the world, primarily in Scandinavian countries, New Zealand and the United States; it is the so-called “no fault - no guilt” model or “no fault compensation scheme”.

In Sweden, mandatory *no-fault* insurance was introduced in 1975. Insurance payers are public healthcare providers and they pay the insurance premium. The patient is compensated for damage based on physical or mental injury, along with the need to prove the causal link between the medical services and injuries. The compensation includes both pecuniary and nonpecuniary damages. An injury report is usually submitted by a medical staff, but the patient can also contact the insurer directly. If the patient is dissatisfied with the amount of remuneration that he/she has been entitled to, he/she can file a claim to the court; however, if the patient loses the lawsuit, he/she is exposed to risk of paying costs of legal proceedings. This system also ensured physicians against consequences of their professional liability in a form of annual payments to a special fund. The system is not based on the subjective liability of a physician for damage that involves the determination of the perpetrator’s guilt. This is an administrative dispute and not civil lawsuit (Proso, 2009: 364). Other Scandinavian countries also have very similar models of patient compensation systems. In Finland, this system was introduced in 1970, first as a voluntary system, while the mandatory model was introduced in 1980. Norway adopted a similar legal regulation in 2003 (Ćepulić, 2008: 130). The Swedish patient insurance model was used as the foundation for drafting similar legislation in Denmark (Proso, 2009: 365).

The United States has reached an unprecedented level of healthcare costs and without signs of slowing growth rates, which leads to the practice of “defensive medicine” (Kessler, 2004: 3), i.e. the application of those treatment options that are not necessarily in the best interest of the patient but have the purpose of protecting the physician from potential court proceedings. That is why there is a need for a reform that would reduce healthcare costs and provide patients with compensation for sustained damage as an alternative to the existing common-law compensation liability system. One of the alternatives¹⁰ is a *no-fault* system

10 In addition to the *no-fault* model in the United States, Medical Responsibility System, a series of *guidelines-based systems* and *binding alternative dispute resolution* are considered. The *guidelines-based system* is based on written guidelines that determine the best treatment of certain illnesses. If physicians and hospitals harmonize their actions with clinical practices from the guidelines, it would be presumed that they are not liable for damage. *Binding alternative dispute resolution* is an agreement between the healthcare provider and the patient

accepted in Florida and Virginia, in a limited scope- for certain neurological injuries related to childbirth. The system compensates the plaintiff with medical expenses and reasonable attorney fees. The system represents an administrative mechanism instead of court compensation, regardless of negligence or medical error. The Virginia system also allows for compensation for lost earnings for people aged 18-65 in the amount of 50% of the average wage (Kessler, 2004: 19-21).

3.1. Medical Error Registration

A common feature of all no-fault systems is that medical errors need to be registered. This is because the evidence of the medical error and the consequences it has caused is aimed at avoiding similar situation in the future. This also provides for high transparency of the health system (Proso, 2009: 369), which is a comparative advantage over other compensation liability models. Such an arrangement is based on the idea that medical errors are unintentional in a vast majority of cases. The system requires the registration of any medical errors and reporting on any technical defect in order to prevent their reoccurrence. By introducing computerization, the code of conduct for diagnostic and therapeutic procedures, and error registration systems, it is possible to analyse and take measures to ensure medical errors are not repeated.¹¹No-fault systems have the purpose of reporting any harmful event during medical procedures, without seeking the quilt (fault) of healthcare professionals, except in case of intent or extreme neglect. These compensation systems have the potential to prevent future mismanagement and provide quick and fair financial compensation without long-standing court proceedings and high costs (Ćepulić, 2008: 130).

4. Concluding Considerations

Applied in any form, the objective liability system relieves physicians and other healthcare professionals of the inconvenience of being subjected to determination of quilt (fault) as a subjective element of liability for damage (Crnić, 2008: 140).

to submit their disputes relating to the damage from medical errors to a third party instead of a court. This system compensates the injured party faster and at a lower cost (Kessler, 2004: 13 – 17).

¹¹ Registering and analysing errors and taking measures preventing the possibility of error has shown exceptional results in the United States. Surgical infections decreased by introducing perioperative antibiotic protocols; the number of incorrect drug prescriptions was reduced by introducing computer programs into medical practice; the number of pneumonia cases was reduced by introducing ventilation control protocols etc. (Ćepulić, 2008:128).

In the Republic of Croatia, the applicable law for damage incurred to a patient in the provision of health services are the general rules on liability for damage envisaged in the Obligation Relations Act (ORA). The prevailing view in the Croatian legal theory and jurisprudence is that liability for damage in healthcare should be judged on the basis of principle of fault (subjective liability). Subjective liability for damage, especially in the area of liability for damage in medicine, can receive certain objections, especially concerning the particularly difficult position of a patient who, as a non-expert, must prove the violation of the rules of a highly specialized profession and the existence of a causal link between the medical error and the damage sustained. This is particularly problematic since experts in these cases are doctors, whose impartiality, for obvious reasons, may be questioned.

In that sense, there are increasing tendencies to introduce a system of objective liability for damage in medicine. In the system of objective or causal liability, in order to determine liability for damage, the court does not have to establish the perpetrator's guilt. In case of damage caused by dangerous goods or hazardous activities, the injured party does not need to prove the causative relationship since that relationship is presupposed. It is precisely in regard to damage caused by hazardous goods or activities in medicine where we see the most intense tendencies for the application of objective liability for damage. This is based on the reasons for the increasingly frequent use of certain devices and the introduction of technology in medicine that did not exist until recently (laser, robotic surgery, radiation, etc.). In such situations, it is necessary for the court to determine in each individual case whether a particular dangerous object or activity which entails an increased risk of damage to the environment was the cause of the particular damage. In that case, the court must apply the rules of objective liability. Legal considerations on the recognition of patients' right to compensation for damage by applying the principle of objective liability are beginning to appear in our legal theory and jurisprudence.

In this respect, the decisions of the Constitutional Court of the Republic of Croatia U-III-1062/2005 of 15 November 2007 is of particular importance. The Constitutional Court confirmed the view of the municipal and the county court that the apparatus for conducting physical therapy with galvanic current by its properties, purpose and position is a dangerous object, and that the therapeutic procedure of using galvanic current is a dangerous activity, which makes the person performing that activity liable for damage resulting from that activity. This decision of the Constitutional Court of the Republic of Croatia is the basis for changing the practice of regular courts when it comes to liability for damage incurred to patients by a hazardous object or activity.

Around the world, primarily in Scandinavian countries, New Zealand and the United States, a new principle for compensating patients was introduced, the so-called “no fault - no guilt” model or “no fault compensation scheme”.

In Sweden, mandatory *no-fault* insurance was introduced in 1975. Insurance payers are public healthcare providers and they pay the insurance premium. The patient is compensated for damage based on physical or mental injury, along with the need to prove the causal link between medical services and injuries. The compensation covers both non-pecuniary and pecuniary damage. Other Scandinavian countries also have very similar models of patient compensation systems. In Finland, this system was introduced in 1970, first as a voluntary one, and the mandatory model was introduced in 1980. Norway adopted similar legislation in 2003. The Swedish patient insurance model was used as the foundation for drafting similar law in Denmark. In the USA, there is a need for a reform that would reduce healthcare costs and provide patients with compensation for sustained damage as an alternative to the existing common-law compensation liability system. One of the alternatives is a no-fault system accepted in Florida and Virginia in a limited scope - for certain neurological injuries related to childbirth.

A common feature of all no-fault systems is that medical errors need to be registered. This is because the evidence of the medical error and the consequences it has caused is aimed at avoiding similar situation in the future. This also provides for a high transparency of the health system, which is a comparative advantage over other compensation liability models. No-fault systems have the purpose of reporting any harmful event during medical procedures, without seeking the quilt of healthcare professionals, except in case of intent or extreme neglect. These compensation systems have the potential to prevent future mismanagement and ensure quick and fair financial compensation without long-standing court proceedings and high costs. Applied in any form, the objective liability system relieves physicians and other healthcare professionals of the inconvenience of being subjected to determination of quilt as a subjective element of liability for damage.

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ОБЈЕКТИВНА ОДГОВОРНОСТ ЗА ШТЕТЕ У МЕДИЦИНИ И ПРЕВЕНЦИЈА ПОВРЕДЕ ПРАВИЛА ЗДРАВСТВЕНЕ СТРУКЕ (ЛИЈЕЧНИЧКЕ ГРЕШКЕ)

Резиме

У правној теорији и судској пракси, у Републици Хрватској, превладава стајалиште да се одштетна одговорност у здравственој дјелатности треба просуђивати према начелу кривње. У односу на штете које у медицини настану у вези с опасном ствари или опасном дјелатности најинтензивније су тенденције за примјену објективне одговорности за штету. У том смислу, од посебног значаја је одлука Уставног суда Републике Хрватске која представља основу за промјену судске праксе редовних судова када се ради о одговорности за штету проузрочену пацијенту опасном ствари или опасном дјелатности. У свијету се, прије свега скандинавским земљама, Новом Зеланду и Сједињеним Америчким Државама, почео примјењивати принцип накнађивања штете пацијентима који се назива „no fault – no guilt“ модел („нема грешке – нема кривње“) или „no fault compensation scheme“ (компензацијска схема без тражења кривње). Ради се о административном, а не грађанскоправном поступку. Свим no-fault суставима заједничко је да се медицинске грешке морају регистрирати како би се сличне ситуације избјегле у будућности. Ови модели остварују високу транспарентност здравственог сустава и имају за циљ брзу и праведну финансијску накнаду без дуготрајног судског поступка и високих трошкова.

Кључне ријечи: штета, медицина, одговорност за штету, лијечничка грешка, no-fault.