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STRICT PRODUCT LIABILITY OVER MEDICAL CARE PROVIDERS: WHAT'S THE STATUS IN CURRENT USA LAW?

In most legal systems, at the current level of development of legal relations, there is a tendency view for the damage caused by the deficiency of products, and it existed at the time of its selling period, objectively its producer bears the responsibility. Besides an evident fact that medical means have product's character, there is a question related to damage a patient suffers from a medical means with deficiency, can besides a producer, also be responsible a health employee/health institution that by using such means caused damage to a patient. Although, with the effort of health employees, responsibility for this damage has been mostly on producers of medical means, where they had the support of a court practice, it is evident there is also a higher need for health employees/ health institutions to be responsible for this damage.

Key words: Medical employee; Medical means with deficiency; Damage; Strict product liability for damage.

1. INTRODUCTION

We are witnesses for the contemporary medicine cannot be imagined without highly sophisticated medical means. The production of medical means is increased day after day for the circumstances that contemporary researches discover the knowledge that certain medical means can prevent appearing of a disease or eliminate more numerous health diseases in the contemporary time. With the increase of medical means number, in the area of health services, there is more transformation in the nature of a doctor's profession and it used to consist of exclusively offering of health services, to a profession that means a transfer of a huge number of medical means.[1]

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[1] R. Adler, "Device Dilemma: Should Hospitals be Strictly Liable for Retailing Defective Surgical Devices?", *Albany Law Journal of Science & Technology* 1994, 96; R. Willis, "Strict

Pursuant to the change of the role of medical employees during the time, legal doctrine has also changed and its teaching on the responsibility of health employees for a damage caused to patients.[2]

In the past, the relation for a responsibility for damage from medical means with deficiency and hospitals was contradictory and opposite. This statement was valid for the circumstances that a hospital did not have a function of a products' seller, but it represented an institution where you treated patients, and thus, hospitals did not have any strict product liability for a damage caused by products with deficiency.[3] However, today, when health industry has changed completely, the reasons that "held" strict product liability out of hospitals are not so convincing. Contemporary hospitals, besides offering services, are engaged in supply and delivery of medical means that in a large number of cases represent the essence of "a transaction" between a doctor and a patient.[4] However, in the past decades, these changes have not been followed either by legal systems, nor court practice. Hence, most courts refused to apply strict product liability of a hospital for damage from medical means with deficiency.[5] For that aim, we shall analyse a line of foreign decisions, mostly court decisions of the legal systems in the USA that either in a positive or a negative way have called in question expanding of strict product liability for damage from medical means with deficiency onto hospitals.

2. THE CONS ARGUMENTS FOR EXPANDING OF STRICT PRODUCT LIABILITY FOR DAMAGE TO MEDICAL EMPLOYEES

Legal theorists did not have a unique answer onto the issue whether strict product liability for damage from medical means with deficiency should also be expanded to hospitals. A similar situation ruled within court practice where, in the beginning, a firm view was taken against this solution.[6] Court decisions that decisively refused a possibility for hospitals to be objectively

Products Liability and Hospitals: Liability of the Modern Hospital and the Use of Surgically Implanted Medical Products, Tools, and Prosthetic Devices", *Western State University Law Review* 2007, 191.

[2] J. Kitsmiller, "Missouri Products Liability Is Budding (Again): Budding v. SSM Healthcare System and the End of the Strict Products Liability Cause of Action against Hospitals", *UMKC Law Review* 2001, 677.

[3] R. Willis, 191; R. Cupp, "Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Product Transactions", *Florida State University Law Review* 1994, 879.

[4] R. Adler, 96.

[5] *Ibid.*

[6] R. Willis, 191.

responsible for damage from medical means with deficiency were in favour to opponents of expanding the responsibility. Courts traditionally treated hospitals and health employees as health service providers. Besides the fact that health employees regularly used, and hospitals provided routinely different products during a patient treatment, hospitals and doctors were not characterised as traders or sellers of these products.[7]

Numerous theorists presented a line of reasons why strict product liability for medical means with deficiency should not be expanded to medical employees. The arguments of legal theory can be concisely presented with the following reasons: 1) the services and products patients get from medical employees are of the essential value for a society in whole. Expanding of responsibility onto medical employees would also increase the prices paid by final users, and in this way, necessary medical instruments and other medical means would be unavailable to poor citizens;[8] 2) strict product liability could influence to a certain number of medical experts to stop providing certain health services and stop providing patients with certain medical means.[9] Having in mind the significance of health work for a society in whole, it must be avoided a possibility for expanding strict product liability onto medical employees;[10] 3) it is not a real selling when doctors use defective products in combination with their services;[11] 4) during providing health services, the essence is in providing treatment services, not selling of products while having an intervention. Selling of medical means is an irrelevant and a bumpy consequence of providing health services. Patients, before all, are interested in a doctor's knowledge, expertise and outcome, not medical means and instruments a doctor uses while having in intervention;[12] 5) for a circumstance that medical professionals have a relatively small base of clients, transferring of responsibility onto them has a smaller effect that onto other traders who usually have a wider clients' base;[13] 6) different from other traders, medical experts can be unable to get a damage compensation from producers since they do not know, in most cases, who has produced a product they use;[14] 7) there is a potential danger of harming a doctor's repu-

[7] R. Adler, 99.

[8] R. Cupp, 889–880; L. Pleicones, "Passing the Essence Test: Health Care Providers Escape Strict Liability for Medical Devices", *South Carolina Law Review* 1999, 475.

[9] K. Posner, "Implantable Medical Devices and Products Liability", *Food, Drug, Cosmetic Law Journal* 1981, 633.

[10] Newmark v. Gimbel's, Inc., 258 A. 2d 697, 702–03 (N. J. 1969).

[11] D. Crump, L. Maxwell, "Should Health Service Providers Be Strictly Liable for Product-Related Injuries? A Legal and Economic Analysis", *Southwestern Law Journal* 1982, 36–40.

[12] R. Cupp, 880; K. Posner, 633.

[13] L. Pleicones, 475.

[14] R. Cupp, 881.

tation and hospital in a case of imposing responsibility regardless of guilt;[15] 8) a lot of producers create for consumers a false feeling of safety through advertising. This fact cannot be taken as a reason of expanding strict product liability onto medical employees, since they usually do not advertise medical means and services.[16]

For the stated reasons, medical employees who do hybrid jobs, providing services and selling of certain medical means, e. g. implants, should not be made objectively responsible for damage with such medical means with deficiency.

2.1. Court Decisions Being Refused to Have a Possibility of Expanding Strict Product Liability for Damage onto Medical Employees

The first decision to start reconsidering the reasons the courts have been led by when they refused a possibility of expanding strict product liability for damage from medical means with deficiency onto medical employees was the decision brought in the case *Magrine v. Krasnica.* In this case, a prosecutor was hurt when a hypodermic needle broke during a surgery intervention and it hurt the prosecutor. By the decision of New Jersey Court, it was refused a possibility of expanding strict product liability onto the dentist. The Court started with a statement that the essence of "the transaction" is between a seller of a product and a consumer in the product itself. The seller performs selling and it is the essence of his work. Exactly this, and only this, is paid. However, to a dentist or a doctor who provides certain health service, it is only paid for his professional work and skills. And pursuant to the Court opinion, it is also the essence of the relation between him and a patient.[17]

One of the most significant decisions being refused a possibility of expanding strict product liability for damage from medical means with deficiency onto medical employees is the decision of the Appellation Court in California, in the case *Carmichael v. Reitz.* In this case, the Court emphasised that medical employees are only channels in the chain of distribution of medical means from producers to patients and thus, they must be exempted from strict product liability. This decision served as a logical base for all future justifications of exemption of hospitals from strict product liability for damage from medical means with deficiency.[18] The logic against expanding of strict product liability onto medical employees the Court then expanded in the case *Silverhart v. Mount Zion Hospital,* where it is emphasised that the hospital does not usually sell any medical means or equipment that is used

[15] K. Posner, 633.

[16] R. Cupp, 881.

[17] Magrine v. Krasnica, 227 A. 2d 539 (N. J. Co. 1967).

[18] Carmichael v. Reitz, 95 Cal. Rptr. 381 (1971).

while providing health services. The essence of a relation between a hospital and a patient is not related to any medical product or equipment, but to the services a hospital provides.[19]

Although in 1970s it was established a base of irresponsibility of hospitals for damage from medical means with deficiency, the most significant step in direction to expanding of cases where a hospital is exempted from responsibility for damage caused as a consequence of using certain implantable medical means, was done in 1980s, in the case *Hector v. Cedars-Sinai Medical Cente.* Hence, the Court emphasised the essence of a relation between a hospital and a patient is providing expert medical service necessary for an adequate pacemaker implantation. A patient does not enter to a hospital just to buy a pacemaker, but to get a treatment that includes pacemaker implantation. As a service provider, and not as a seller of products, a hospital is not responsible based on strict product liability for defective products provided to patients during their treatment.[20] Also, in the case *North Miami General Hospital v. Goldberg,* the Court explained that the hospital cannot be objectively responsible for damage compensation since a circumstance that it was not a seller of defective medical means.[21] There is a similar explanation of the Court decision in the case *Podrat v. Codman-Sburtleff, Inc.,* where it was determined for the hospital it was not objectively responsible, for the hospital does not do selling of medical instruments. The use of medical instruments, the Court stated, was only irrelevant compared to a primary function of providing health services.[22] In the case *Easterly v. Hospital of Texas, Inc.* and *Vergott v. Desert Pbarmaceutical Co*, the Courts refused to expand strict product liability onto hospital and doctors for damage caused by a defective catheter. Also, the Court determined that the use of a radiation treatment is not selling of products and refused to expand strict product liability for a defective radiation treatment.[23]

2.2. Health Profession: Selling of Products or Providing Services

During making the stated decisions, where it was reconsidered the issue of expanding strict product liability for damage from medical means with deficiency onto hospitals, the Courts were forced to reconsider the issue wheth-

[19] Silverhart v. Mount Zion Hospital, 20 Cal. App. 3d at 1027. (1971).

[20] Hector v. Cedars-Sinai Medical Center (1986), 180 Cal. App. 3d 504.

[21] North Miami General Hosp., Inc. v. Goldberg, 520 So. 2d 650, 13 Fla. L. Weekly 509 (Fla. App. 3 Dist., 1988).

[22] Podrat v. Codman-Sburtleff, Inc., 558 A.2d 895 (Pa. Super. Ct.), alloc denied, 569 A. 2d 1368 (Pa. 1989).

[23] Easterly v. Hospital of Texas, Inc., 772 S. W. 2d 211 (rex. Ct. App. 1989) and Vergott v. Desert Pbarmaceutical Co. 463 F. 2d 12 (5th Cir. 1972).

er hospitals are characterised as sellers of products or as service providers. In fact, the old system of values was abandoned that experienced hospitals as charitable institutions and Courts started to re-examine a new function of hospitals: hospitals as companies.[24] On the one side, the initiated view emphasised the fact that health care today counts such things as medicines, medical means, blood, and also organ transplantation, etc. However, hospitals also provide health protection and, in correlation with powers, this fact stands on the other side. In the essence, when the responsibility of medical employees is on for damage from medical means with deficiency, a question can be asked whether in a certain health protection prevail goods or services?[25]

We saw the Courts, in each of the stated cases, established a parallel between *selling of products and service providing*, and they brought decisions depending on the essence of relations prevailing among hospitals, i. e. doctors and patients. Generally, it was confirmed that the essence of a relation between a doctor-patient makes providing of services, with the ascertainment that a hospital's work cannot be characterised as selling of products. Based on this, the Courts refused to expand strict product liability for damage from medical means with deficiency onto hospitals.[26]

Health profession contains in itself, both service providing and selling of certain products, and it is impossible to establish a clear distinction between them. We can only talk on what prevails during a health "transaction", whether it is selling of products or service providing; i.e. clearly speaking, the answer should be sought in the question what makes the essence of a certain health "transaction", is it a certain product or, still, a certain service?

3. THE PRO ARGUMENTS FOR EXPANDING STRICT PRODUCT LIABILITY FOR DAMAGE ONTO MEDICAL EMPLOYEES

The Courts refused a possibility of expanding strict product liability for damage from medical means with deficiency during making their decisions and they used a test where it was evaluated the essence of a medical "transaction". Pursuant to the prevailing work of Court decisions, the essence of a medical "transaction" consists in providing health services, not in selling of medical means. However, the result of the test cannot be the same for all types of medical means. Medical means, such as a heart valve and other implantable means, then a false hip bone, knee or some other prosthetic medical means do not give enough arguments that the essence of a "trans-

[24] J. Kitsmiller, 679.

[25] J. Kitsmiller, 679; L. Pleicones, 471.

[26] D. Crump, L. Maxwell, 831–834; D. Ryan, L. Timothy, "Strict Liability Claims against Health Care Providers in Breast Implant Litigation", *Tort & Insurance Law Journal* 1994, 823; J. Kitsmiller, 679–680

action" between a patient and a doctor is in providing services.[27] Indeed, it can be noticed, from a number of cases, where Courts refused to expand strict product liability onto hospitals, it was the case on disputes where the damage was caused by medical instruments with deficiency, and based on this, it was reconsidered the essence of a medical "transaction". Pursuant to this, a general view that medical employees should be exempted from strict product liability for damage from medical instruments with deficiency was applied to all medical means. The Courts, literary, except in few decisions, missed to make a line of separation between different medical means.[28]

Even if we start from Courts' decisions that refused a possibility of expanding strict product liability for damage from medical means with deficiency onto medical employees, it can be concluded they also know on the usage of expanding strict product liability.[29] If nothing else, they emphasised what the Courts were relied on when they brought decisions where they refused expanding of strict product liability onto hospitals. In fact, an argumentative question can be asked on what is the essence of a "transaction" between a patient and a doctor when a patient goes to hospital in the aim of having his prosthetic of a knee or a hip done, whether the essence of a "transaction" is in service or in the prosthetic itself? If we reconsider a "transaction" from the aspect of a patient, for him the essence of a "transaction" is in prosthetic, its characteristics and conveniences, not in the skill of a doctor and his expertise.[30]

The skill and expertise of a doctor cannot vary drastically, these are educated people with a certain expertise education, and if there is an adequate system of education, it cannot be said on drastically high oscillations in the expertise of health employees. It is more spoken on oscillations regarding the quality of certain medical means, where depending on certain circumstances their quality can drastically vary, and a patient is mostly interested in the medical means only, its quality and function, while a doctor's service is an accompanying circumstance that is implied in. This is especially emphasised with implantable medical means, such as pacemakers. The operation on a heart cannot be done by any doctor, it is understood they are highly expert persons with expert knowledge, and it is every patient accounts for regarding heart problems, where it is necessary to have a pacemaker implantation and leaving to hospital. For a patient, firstly, he is interested in the function and quality of a pacemaker. Also, there is no possibility for a pacemaker to be in a heart of a patient without hospital and expert doctor. Hospitals and doctors are, in this context, the basic line of medical means distribution.

[27] R. Adler, 104.

[28] L. Pleicones, 478.

[29] R. Cupp, 891.

[30] R. Adler, 104; L. Pleicones, 472 and 477.

The pro regarding expanding of strict product liability for damage from medical means with deficiency onto hospitals is the circumstance of a primary importance, among numerous issues hospitals face with, and it is a direct responsibility of a hospital for the quality of protection offered to patients in their frames.[31] Pursuant to the opinion of certain theorists, hospitals are not considered only as buildings any more within a group of doctors who take care of patients' health. The functions of hospitals is changed drastically and they have a fundamental role in protection of citizens' health today.[32] If certain issues are reconsidered such as health protection costs, the increase of health management system, efforts of obligors to reduce spending of health system and similar; hospitals seem more like companies to compete for their part in the market.[33] Today, they represent some of the leading companies in the world and act in the same way as other economy institutions; they spend a huge amount of money onto posters every year, TV advertisements, mail, newspaper advertisements and similar; all in the aim of stimulating future patients to choose their institution for different disease treatment.[34]

Regardless whether a patient buys a medical service, medical means or both, a giver of health services is in the same position towards a patient in several ways, both as a seller towards a consumer. An average buyer of health services (and products) cannot estimate the quality offered to him, since certain health services and products are complex and are seldom to be bought.[35] The medical means market gives little information on patients as users of health services based on whom they could estimate the quality of a medical product to be bought.[36] However, an average user of health services cannot estimate the quality of health service, either the quality of health products, regardless which market offers to him medical means. In this context, the information patients receive from doctors are crucial in their choice, both for a medical treatment and medical means, and also medical means to be used at the same one. A doctor, not a patient, determines what services and what medical products to make sure for a patient.[37]

Pursuant to the stated, doctors are in a better position to estimate and compare the quality of services and medical means to make sure for a patient, and relying of a patient onto expertise, knowledge and skills of a doc-

[31] P. Scibetta., "Note, Restructuring Hospital-Physician Relations: Patient Care Quality Depends on the Health of Hospital Peer Review", *51 U. PITT. L. REVIEW*, 1990, 1025.

[32] *Ibid.*, 1026–1027.

[33] R. Adler, 125.

[34] J. Kitsmiller, 683–684.

[35] R. Adler, 125.

[36] Hoven v. Kelble, 256 N. W. 2d 379, (Wis. 1977).

[37] *Ibid.*

tor is in a higher degree bigger than relying of consumers onto sellers of non-medical products.[38]

Hospitals, generally, have a freer choice of medicines, medical means and other medical products. In fact, a hospital can freely choose medical means of a certain producer. Opposite of this, patients seldom have a chance to choose a hospital where they will get a certain health service, and even more seldom, what medicine or medical means will be used during their treatment. Pursuant to the stated, if strict product liability for damage from medical means with deficiency would expand only onto hospitals, the consequence would probably be, buying only the best products at the market by hospitals, causing production of more qualitative medical means by producers.[39]

The fact should be emphasised that most medical means cannot be produced without knowledge and doctor's participation in the planning process and construction of medical means. The knowledge of a doctor on causes of certain disease, consequences that appear, methods to prevent disease origin, removal of consequences of a disease are in most cases crucial for construction of a certain medical means. A doctor's suggestions are a transient base in production of medical means. Also, with a certain number of medical means producers can only be hospitals.

The argument of opponents of expanding strict product liability that producers create a false feeling of safety among consumers through advertising and this fact cannot be taken as the reason of expanding strict product liability onto medical employees, since they usually so not advertise medical means and services, and it is not valid any more for the circumstance of being old-fashioned.[40] Contemporary hospitals definitely do advertising of their services and medical products through television, radio, different publications, Internet and so on. All these types of novelties are full of content speaking on plastic surgery and implants they use. Beauty is of high importance and one of the most frequent ways to accomplish a desirable look is through plastic surgery and it includes a huge number of implantable medical means.

One of the primary reasons for strict product liability of a company is the circumstance they are profitable organisations and by selling products gain profit that allows to them the best position in allocation of costs on compensation of injured persons.[41] This argument was used as a counterbalance to expanding strict product liability onto hospitals for the circumstance they were, the most often, small charitable institutions with a few doctors and they were not able to amortise a risk of expanding of strict product liability for damage.

[38] *Ibid.*

[39] R. Adler, 109.

[40] R. Cupp, 881.

[41] L. Pleicones, 483.

Today, however, this statement is not valid any more, since hospitals are most often organised as profitable companies that gain enormous profit, and a huge part of this profit gain thanks to distribution of medical means.[42]

The opponents of expanding strict product liability for damage from medical means with deficiency emphasise the most the circumstance that services and products patients receive from medical employees are of essential value for a society in whole, and by expanding responsibility onto medical employees would increase the prices they pay as final consumers, and in this way, necessary medical instruments and other medical means would be unavailable to poor citizens.[43] This conclusion is wrong from several reasons. Firstly, there are other products besides medical means of essential value for a society in whole, e.g. food products that are not exempted from strict product liability, and this circumstance does not influence onto price increase and their availability to poorer citizens.[44] Secondly, we know contemporary hospitals are organised as companies and with their capacities they have a tendency to gain a maximal competition in the market. The increase of service prices and medical means products would not be appropriate to hospital competiveness and to their aim of attracting a higher number of patients.[45]

If the argument of opponents towards expanding strict product liability would consist in the fact that hospitals do not participate in development and production of medical means, and thus, they are not in a position to stop circulation of medical means with deficiency, an efficient counter-argument could be found in the circumstance that neither sellers of products are in the position to influence development and production of products, but they have their place in the chain of distribution and they can influence onto producers to produce more qualitative products in the way to refuse to buy a product that is not completely checked, tested or if they bear recognisable risks to their users.[46]

Looking this way, a seller does not have a direct control over development and production of products, but surely, indirectly, can contribute to improvement of products' safety.[47] All stated is also valid for hospitals as distributers of certain medical means, with a difference a hospital in the context of influence onto production of more qualitative medical means is more influential and more responsible compared with ordinary sellers of products. The fact is that hospitals are the only channel through which patients can receive certain, most often, implantable medical means.[48]

[42] *Ibid.*

[43] R. Cupp, 879–880; L. Pleicones, 475.

[44] L. Pleicones, 484.

[45] *Ibid.*

[46] *Ibid*., 485.

[47] *Ibid.*

[48] *Ibid.*

Another pro circumstance to expanding strict product liability for damage from medical means with deficiency onto medical employees lies in the statement that a frequent consequence of strict product liability of a producer for damage from products with deficiency is bankruptcy of a producer itself.[49] Production of certain products is most often a serial character and a number of products have the same deficiency and a number of consumers suffer the same damage consequences. A huge number of demands for damage compensation most often lead producers to bankruptcy, so patients would bear all harmful consequences if hospitals would be exempted from strict product liability for damage from medical means with deficiency.[50]

We emphasised that a huge number of Court decisions where it is not accepted strict product liability emphasises as a reason that the essence of a medical "transaction" between a doctor and a patient makes any medical service. The Courts had a view regardless that a certain medical "transaction" means distribution of medical means, the essence of a "transaction" lies in the service, not in the product, since there is no distribution of medical means without a doctor's service. This view can be annulated very simply by a simple statement that there is no medical intervention without the existence of certain medical means and exactly their existence allows a given intervention and curing of a number of diseases in the contemporary society. Medical means is the essence of a huge number of medical "transactions", whether we admit it or not, and medical means will be the primary base in improvement of health of a human society. It seems we are in front of the door of the time where medical means will exist and independently perform a certain medical intervention, and doctors will be only observers in it.

Besides stated, the fact is that transferring of medical means is not the primary function of a hospital, and it should not be a key argument in exempting of responsibility of a hospital for damage from medical means with deficiency.[51]

4. THE PRO COURT DECISIONS OF EXPANDING STRICT PRODUCT LIABILITY FOR DAMAGE ONTO MEDICAL EMPLOYEES

For the beginning of analyse of pro Court decisions for expanding of strict product liability onto medical employees, we shall take the decision reconsidered by Rachel Adler in his paper, and it is a denied possibility of expanding strict product liability. In the case *Ruybe v. Gordon* the Court is, during a test application based on whom it is estimated what is the essence

[49] *Ibid.*, 486.

[50] *Ibid.*

[51] Karibjanian v. Thomas Jefferson Univ. Hosp., 717 F. Supp. 1081, 1085 (E. D. Pa. 1989).

of a "transaction" between a doctor and a patient, stated that the doctor who did implantation of a spiral to a patient, did not become a seller for the device he implanted. According to the opinion of Rachel Adler, the Court was at least mistaken during such statement. A woman who goes to hospital for contraception does not have a need for treatment, but she has a need for medical means called a spiral. If the spiral represents the essence of a "transaction", how is it, pursuant to the Court statement, to represent only a secondary device and not a primary part of a medical intervention?[52] The peculiarity of this case is the essence of a relation between a doctor and a patient makes only a medical means since a patient does not have any disease, and she is not interested in treatment, she only has in her mind a medical means, its function, quality and efficiency. Also, the only way for such medical means to be sold and come to a consumer is a doctor's intervention. Based on this case, we can state that medical employees are the primary link of distribution and the Court was wrong when it refused to expand strict product liability onto the hospital since the damage the patient suffered for medical means deficiency.

As pro circumstance to expanding strict product liability for damage since deficiency of certain medical means onto medical employees, Rachel Adler states the explanation of the Court decision from the famous Court dispute *Silverhart v. Mount Zion Hosp.* Indeed, in her opinion, and we think it is justifiable, the decision explanation is completely correct when it is the issue of medical instruments. However, when most of implantable medical means is under issue, the explanation of Court decision must have a completely new dimension.[53] Producers of medical means, as a final user of implantable medical means, only have in mind a patient himself. A hospital is only a link in the chain of distribution and it is the only link in the chain of distribution between a producer and a patient, as a final user of implantable medical means.[54] We shall expand this argument with the statement that hospitals in such cases have a huge part in advertising implantable medical means. Doctors are the ones who recommend an implant to a patient, explaining it by its certain quality, function and reliability of medical means. A huge number of patients do not have any idea on most medical means, and even less on implantable medical means. Doctors are the ones who introduce patients on the significance and role of certain medical means. Most patients never pay attention to advertisement of any medical means until a certain disease appears. And when it is the issue of treating of a certain disease, measures to be taken and means to be used, a doctor's opinion is innocuous.

[52] R. Adler, 105.

[53] *Ibid.*, 106.

[54] *Ibid.*

It is interesting that Court practice in the cases where hospitals and health doctors were not included was ready to expand strict product liability onto cases that include both selling of products and providing services. Only two years after the of case *Magrine v. Krasnica,* the Supreme Court in New Jersey brought a decision for the beauty salon that performed its treatments with deficiency products for hair care and claimed it objectively responsible for the damage a treatment user suffered.[55]

Court decisions where it was reconsidered doctors' responsibility for infections to patients since they used infected blood can serve as good pro argument to expanding strict product liability for damage from medical means with deficiency onto medical employees. Long ago, in 1954, the Appeal Court in New York concluded that a blood transfusion service is a "transaction", and pursuant to it, there is no possibility to add to it selling guarantees.[56] Most courts followed this decision, where in the selling/service analyse, it was concluded it was the service of "transaction".[57] However, this condition lasted until 1970, when the Supreme Court of Illinois bravely, and pursuant to our opinion, with arguments, digressed from the entire Court practice and concluded that the hospital does selling business of *blood selling* for patients' transfusion, and pursuant to it, the doctrine of strict product liability is valid for hospitals, too. The Court statement was clear, *blood is a product*, and hospitals are included into *distribution chain* of this product.[58]

As a reason for expanding strict product liability onto medical employees can serve a decision of the Court in California where strict product liability was imposed to a doctor who missed to warn his ex-patient on additionally discovered dangers related to implanted intra- uterine means, although he was not the doctor of the treated patient any more.[59]

The Supreme Court of Alabama, in the case *Skelton v. Druid City Hospital Board*, had his view for the first time in the Court practice in the USA that a hospital can be characterised as a seller, and stated that in the essence, hospitals are traders. In this Court dispute, the patient sued hospital for the broken needle and it stayed in the patient's body during his hernia operation. The Court emphasised: we cannot ignore the fact that hospitals are, regardless of being profitable or not, companies. They are not only buildings that offer for placement for seriously ill patients and independent doctors. During their competition, hospitals are presented as public institutions that own knowledge in providing services to patients. The consistent element

[55] Newmark v. Gimbel's Inc., 258 A. 2d 697 (NJ. 1969).

[56] Perlmutter v. Beth David. Hospital, 308 N. Y. 100 (1954).

[57] R. Adler, 122.

[58] Cunningham v. MacNeal Memorial Hosp., 266 NE 2d 89 – Ill: Supreme Court.

[59] Teresmer v. Barke, 86 Cal. App. 3d 617, 150 Cal. Rptr. 384 (1979).

of this presentation is a guarantee to sell, deliver or provide patients with goods used for providing services and they are appropriate for the intended purpose. In this context, a hospital is clearly "a trader" – in the sense this word has a meaning in a business codex.[60]

In the case *Garcia v. Edgewater Hospital,* the Court in Illinois estimated the hospital was responsible for violation of an implicit selling guarantee, since it sold to the plaintiff a deficiency blood valve. Indeed, the Court characterised the hospital as a trader that sold and collected from the plaintiff the deficiency blood valve. In the chain of production and distribution of medical means, the hospital is characterised as the subject that performs selling of products to its patients.[61]

Also, in the Court dispute *Bell v. Poplar Bluff Physicians Group,* the Appeal Court of Missouri claimed the hospital objectively responsible for selling of deficiency surgical implants. Indeed, the Court in this case emphasised that a request for damage from medical means with deficiency should be accepted based on strict product liability towards a seller, regardless whether selling is the essential element of their work or business.[62]

In the explanation of the Court decision of the Supreme Court of Pennsylvania, from the dispute *Cafazzo v. Central Medical Health Servs., Inc*., it is stated that a person who does the basic service should not be made objectively responsible for damage from deficiency means that was of irrelevant character compared to the service itself. From such an explanation, the conclusion would follow that application of strict product liability for damage from medical means with deficiency onto medical employees is justified, when a medical means is the essence of a medical "transaction".[63]

5. STRICT PRODUCT LIABILITY AND THE USE OF MEDICAL INSTRUMENTS, IMPLANTS AND PROSTHETIC GEARS

5.1. Medical Instruments Damages

When we talk on medical instruments, it is simple to establish a difference between *selling of products* and *selling of services*. Surgical instruments are used during an intervention on a patient, and then, depending on the instrument's nature, reject or apply with or without additional conditions on other patients. In essence, a medical instrument stays in a hospital's property or a doctor who has performed a certain intervention and there is not

[60] Skelton v. Druid City Hospital Board, 459 So. 2d 818 (Ala. 1984).

[61] Garcia v. Edgewater Hospital, 613 N. E. 2d 1243 (1993).

[62] Bell v. Poplar Bluff Physicians Group, Inc**.** 879 S. W. 2d 618 (Mo. Ct. App**.** 1994).

[63] Cafazzo v. Central Medical Health Servs., Inc., (Penn. 1995).

any selling of medical instruments, or the expanding of strict product liability for damages from medical instruments with deficiency onto hospitals.[64]

The work of hospitals does not consist in selling of medical instruments. Production and distribution is final when a producer has sold a medical instrument to a hospital, since a hospital is not oriented onto the work of selling of medical instruments to patients, furthermore, it is a final user of a medical instrument.[65] Also, it is impossible to expand strict product liability onto hospitals for damage for the lack of medical instruments, since a key element misses for introduction of strict product liability and it is a circumstance that a hospital does not play an important role in production or advertising of products.[66]

In essence, it is not only the essence of relation between a hospital and patients in providing adequate health services, but hospitals, not patients, are final users of instruments as medical products.[67]

5.2. Implants Damages

When we talk on implantable medical means, the situation is completely different related to medical instruments and it should be determined whether it is on *selling of products* or *providing services*, or perhaps it is a hybrid relation that incorporates both terms.[68] If a pacemaker is necessary to a patient, this implant is the essence of a "transaction" and a patient, not a hospital, is a final user of this medical means.[69] In these cases, a hospital should be made objectively liable for damage a patient suffered since the lack of this implantable medical means.[70] The essence of a medical intervention is the very pacemaker, and then him, not a hospital, is the user of a pacemaker.[71] If we analyse the decision from the case of *Hector v. Cedars-Sinai Medical Cente*,[72] we can make an ascertain on the Court that has made several mistakes. Thus, Adler Rachel claims the Court has made a mistake when it rejected to admit that a hospital has a similar role as a retailer when it "sells" medical means to its patients, since without a hospital, there is no possibility for such a product to reach a patient.[73] Also, Adler Rachel states, the Court in the case of *Hector*

[64] D. Ryan, L. Timothy, 824.

[65] R. Adler, 106; R. Willis, 197.

[66] R. Adler, 106; R. Willis, 197.

[67] R. Adler, 106; R. Willis, 197.

[68] D. Ryan, L. Timothy, 824.

[69] R. Willis. 197.

[70] K. Posner, 633.

[71] R. Willis, 197.

[72] Hector v. Cedars-Sinai Medical Center, 180 Cal. App. 3d 504 (1986).

[73] R. Adler, 107.

v. Cedars-Sinai Medical Cente, has sophistically ignored the fact that the role of a hospital, when using its medical means, is significantly different from the role of a hospital when it sells medical means to its patients.[74]

When we talk on breast implants, it is clear for this medical means is implanted to a patient as a hospital property and in this way, it is transferred to it the right to property, and a patient pays for it. A hospital or a doctor transfers or provides a patient with the medical means with deficiency, instead to use it in the aim of a patient's treatment.[75]

Generally, there are several reasons to justify expanding of strict product liability for damage from implantable medical means with deficiency onto medical employees. They are: 1) hospitals and doctors are buyers of implantable medical means.[76] In the distribution chain of these medical means, hospitals are the basic chain between a producer and a patient, as a final user. Hospitals, most often, buy implantable medical means from producers, and then, through a medical "transaction", sell to patients; 2) patients are not in a position to evaluate or make a choice among different implantable medical means available on the market (although doctors can also have a lack of necessary knowledge for estimation of characteristics of complex technological devices, hospitals and doctors have data necessary for making right decisions);[77] 3) implants are bought in a trading process, where a broad advertising is included in medical journals directed towards doctors and hospitals, and often, sophisticated selling powers.[78] There is vast literature, newspaper articles, textbooks, Internet sites, books of collections and other publications speaking on medical issues, and a huge number of these issues is related to medical means. Based on this, hospitals and doctors are in a position to evaluate the quality and safety of different implantable medical means. Also, it should be mentioned that there are enormous misuses during supply, not only medical means, but also other medical products. Thus, often, from some other lucrative reasons, hospitals and doctors supply consciously medical means that realistically looking at them, do not belong to the most reliable ones; 4) hospitals and doctors are often the only parties aware of the guaranties and quality of the medical means and often, the only subjects that are in a position to evaluate guaranties, safety and security of medical means;[79] 5) it should not be allowed to hospitals and doctors a possibility to allude onto the condition that damage has been a result of unpre-

[74] R. Adler, 107.

[75] D. Ryan, L. Timothy, 824.

[76] K. Posner, 633.

[77] *Ibid.*

[78] *Ibid.*

[79] *Ibid.*

dictable medical circumstances, when a damage cause is directly identified as a technical deficiency.[80]

5.3. Prosthetic Medical Means Damages

When speaking on prosthetic means, the situation is completely clear. If we begin from the tests used by the Courts in the USA during making decisions where they have rejected the possibility of expanding strict product liability for damage from medical means with deficiency onto medical employees, it is certainly to be concluded that the essence of a relation between a doctor and a patient is in prosthetic means that is the object of "transaction", and not in providing expert services of a doctor. [81] If we reconsider the issue from the production aspect, then as a producer, it is mostly a hospital itself, and in most number of cases, a hospital can be a producer of such medical means. On the other side, if we reconsider the issue from the spending aspect, a patient is a person who appears in the role of a final user of prosthetic means, not a hospital. Essentially, regardless of the aspect of reconsidering, expanding of strict product liability for damage from medical means with deficiency onto medical employees, when it is related to prosthetic medical means, it not under any question.[82]

6. CONCLUSION

By the increase of application of technological inventions in the area of providing health services, there is even more transformation of the nature of doctor's profession that means the transfer of a huge number of different medical means. This statement derives from the fact that hospitals are the only channel through whom a patient can be determined certain, the most often, implantable and prosthetic medical means. If a patient is necessary to have a pacemaker, this implant is the essence of "a transaction" and a patient, not the hospital, who is a final user of this medical means. The essence is not that hospitals are the link in the distribution chain of medical means, but they are, most often, the only possible link in distribution of medical means. In these cases, there is a tendency in the Court practice of the USA for hospitals to be made objectively responsible for damage patients suffer since medical means with deficiency. Hospitals are not charitable institutions any more with few doctors and even less patients, they are powerful economic subjects today that earn enormous profit from medical "transactions" that mean distribution of implantable, prosthetic and other medical means.

[80] *Ibid.*

[81] R. Adler, 104; R. Willis, 199.

[82] R. Adler, 104.

LIST OF REFERENCES

Scientific works

1. Adler, Rachel B., "Device Dilemma: Should Hospitals be Strictly Liable for Retailing Defective Surgical Devices?", *Albany Law Journal of Science & Technology* 1994;
2. Willis, Robert R., "Strict Products Liability and Hospitals: Liability of the Modern Hospital and the Use of Surgically Implanted Medical Products, Tools, and Prosthetic Devices", *Western State University Law Review* 2007;
3. David, Crump, Larry A. Maxwell, "Should Health Service Providers Be Strictly Liable for Product-Related Injuries? A Legal and Economic Analysis", *Southwestern Law Journal* 1982;
4. Kitsmiller, Julia D., "Missouri Products Liability Is Budding (Again): Budding v. SSM Healthcare System and the End of the Strict Products Liability Cause of Action against Hospitals", *UMKC Law Review* 2001;
5. Cupp, Richard L. Jr., "Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/ Service Cosmetic Product Transactions", *Florida State University Law Review* 1994;
6. Pleicones, Laura, "Passing the Essence Test: Health Care Providers Escape Strict Liability for Medical Devices", *South Carolina Law Review* 1999;
7. Posner, Kenneth, "Implantable Medical Devices and Products Liability", *Food, Drug, Cosmetic Law Journal* 1981.

Court decisions and internet sources

1. *Newmark v. Gimbel's Inc*., 258 A. 2d 697 (NJ. 1969); Available from: *https://law.justia.com/cases/new-jersey/supreme-court/1969/54-n-j-585-0.html* 6. january, 2022.
2. *Magrine v. Krasnica*, 227 A. 2d 539 (N. J. Co. 1967). Available from: *https://case-law.vlex.com/vid/227-2d-539-n-619970683* 6. january 2022.
3. *Carmichael v. Reitz,* 95 Cal. Rptr. 381 (1971). Available from: *https://casetext.com/case/carmichael-v-reitz* 6. january 2022.
4. *Silverhart v. Mount Zion Hospital,* 20 Cal. App. 3d at 1027. (1971). Available from: *https://law.justia.com/cases/california/court-of-appeal/3d/20/1022.html* 6. january, 2022;
5. *Hector v. Cedars-Sinai Medical Center*, 180 Cal. App. 3d 504 (1986). Available from: *https://law.justia.com/cases/california/court-of-appeal/3d/180/493.html* 6. january 2022;
6. *North Miami General Hosp., Inc. v. Goldberg*, 520 So. 2d 650, 13 Fla. L. Weekly 509 (Fla. App. 3 Dist., 1988). Available from: *https://casetext.com/case/north-miami-general-hosp-v-goldberg* 6. january, 2022;

7. *Podrat v. Codman-Sburtleff, Inc.,* 558 A. 2d 895 (Pa. Super. Ct.), *alloc denied, 569* A.2d 1368 (Pa. 1989).
Available from: *https://law.justia.com/cases/pennsylvania/supreme-court/1989/* 6. january, 2022;
8. *Easterly v. Hospital of Texas, Inc.,* 772 S.W.2d 211 (rex. Ct. App. 1989).
Available from:
http://www.heinonline.org.proxy.kobson.nb.rs:2048/HOL/CaseLaw?cid=3526391&%20cop=&native_id=3526391&rest=1&collection=journals
9. *Vergott v. Desert Pbarmaceutical Co.* 463 F. 2d 12 (5th Cir. 1972).
Available from: *https://www.casemine.com/judgement/us/5914c71badd7b049347e010b* 6. january 2022.
10. Ryan Daniel F. III, Lawn Timothy R., "Strict Liability Claims against Health Care Providers in Breast Implant Litigation", *Tort & Insurance Law Journal* 1994;
11. Scibetta Paul L., "Note, Restructuring Hospital-Physician Relations: Patient Care Quality Depends on the Health of Hospital Peer Review", *51 U. PITT. L. REVIEW* 1990;
12. *Hoven v. Kelble*, 256 N. W. 2d 379, (Wis. 1977).
Available from: *https://law.justia.com/cases/wisconsin/supreme-court/1977/75-452-7.html* 6. january, 2022.
13. *Karibjanian v. Thomas Jefferson Univ. Hosp*., 717 F. Supp. 1081, 1085 (E. D. Pa. 1989).
Available from: *https://casetext.com/case/karibjanian-v-thomas-jefferson-univ* 6. january 2022.
14. *Perlmutter v. Beth David. Hospital*, 308 N. Y. 100 (1954).
Available from*: https://casetext.com/case/perlmutter-v-beth-david-hosp* 6. january, 2022.
15. *Cunningham v. MacNeal Memorial Hosp*., 266 NE 2d 897 - Ill: Supreme Court 1970
Available from: *https://law.justia.com/cases/illinois/supreme-court/1970/42526-5.html* 6. january 2022.
16. *Skelton v. Druid City Hospital Board*., 459 So. 2d 818 (Ala. 1984).
Available from: *https://casetext.com/case/skelton-v-druid-city-hosp-bd* 6. january 2022.
17. *Garcia v. Edgewater Hospital*, 613 N. E. 2d 1243 (1993).
Available from: *https://scholar.google.com/scholar_case?case=13176796347412260099&q=1.+Garcia+v.+Edgewater+Hospital,+613+N.E.2d+1243+(1993).&hl=en&as_sdt=2006&as_vis=*1 6. january 2022.
18. *Bell v. Poplar Bluff Physicians Group, Inc***.** 879 S. W. 2d 618 (Mo. Ct. App**.** 1994).
Available from: *https://scholarship.law.missouri.edu/cgi/viewcontent.cgi?article=3245&context=mlr* 6. january 2022

19. *Cafazzo v. Central Medical Health Services*, *Inc*., 635 A. 2d 151 - Pa: Superior Court 1993.
Available from: *https://law.justia.com/cases/pennsylvania/superior-court/1993/430-pa-super-480-2.html* 6. january 2022.

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OBJEKTIVNA ODGOVORNOST PRUŽAOCA MEDICINSKE NJEGE ZA NEISPRAVNOST PROIZVODA: KAKVO JE TRENUTNO STANJE U PRAVU SJEDINJENIH AMERIČKIH DRŽAVA?

Сажетак

U većini pravnih sistema na trenutnom nivou razvoja pravnih odnosa postoji tendencija u mišljenju da proizvođač treba da snosi odgovornost za štetu prouzrokovanu neispravnim proizvodom. Pored očigledne činjenice da medicinsko sredstvo ima karakter proizvoda, postavlja se i pitanje odgovornosti medicinskog osoblja / institucije za štetu nanesenu pacijentu. Iako odgovornost za štetu uglavnom leži na proizvođaču medicinskog sredstva, što je potvrđeno i sudskom praksom, evidentno je da postoji veća potreba za odgovornosti medicinskog osoblja / institucije za navedenu štetu.

Кључне речи: *Medicinsko osoblje; Neispravno medicinsko sredstvo, Šteta, Objektivna odgovornost za štetu nastalu neispravnim proizvodom*.