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COMPENSATION SCHEMES FOR HEALTH HARM CAUSED BY MEDICAL ERROR: COMPARATIVE LEGAL RESEARCH AND CHOICE OF PATH FOR THE RUSSIAN FEDERATION

PLANES DE COMPENSACIÓN DEL DAÑO A LA SALUD PROVOCADO POR ERROR MÉDICO: INVESTIGACIÓN Y ELECCIÓN JURIDICA COMPARADA DE RUTA PARA LA FEDERACIÓN DE RUSIA

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Abstract:

The purpose of this work is a comparative legal study of foreign experience in legal regulation and practice of applying special schemes for compensation for harm caused to health as a result of a medical error, as well as determining the prospects for the development of Russian legislation in this part. The article examines the regulatory legal acts of the Russian Federation and a number of foreign countries (Belgium, Germany, Denmark, Norway, France, Sweden, the United

Resumen:

El propósito de este trabajo es un estudio legal comparativo de la experiencia extranjera de regulación legal y la práctica de aplicar esquemas especiales de compensación por daños causados a la salud como resultado de un error médico, así como determinar las perspectivas para el desarrollo de la legislación rusa en esta parte. El artículo examina los actos jurídicos reglamentarios de la Federación de Rusia y varios países extranjeros (Bélgica, Alemania, Dinamarca,

Arab Emirates, etcétera.), the practice of their application. Methods used: general philosophical, general scientific, particular scientific, special (formal legal, comparative legal). Of particular value to the study is the fact that the author substantiates the possibility of applying special legal presumptions as an alternative to the use of costly and organizationally problematic no-fault schemes. For the first time, the prospects for the introduction of certain elements of compensation schemes without fault for «accidents» are determined in those areas of medical activity where it is especially difficult to establish the origin of harm from the actions (inaction) of a particular medical worker, including for individual elements of the scheme. As a result, the presented study is relevant and significant not only for Russia, but also for other states that have not yet developed a stable special regulatory legal regulation of these relations.

Keywords:

Compensation, fault, harm, health, liability, scheme.

Noruega, Francia, Suecia, Emiratos Árabes Unidos, etcétera), la práctica de su aplicación. Métodos utilizados: filosófico general, científico general, científico particular, especial (jurídico formal, jurídico comparado). De particular valor para el estudio es el hecho de que el autor fundamenta la posibilidad de aplicar presunciones legales especiales como alternativa al uso de esquemas sin culpa que son costosos y organizacionalmente problemáticos. Por primera vez se determinan las perspectivas de introducción de determinados elementos de los sistemas de indemnización sin culpa de los «accidentes» en aquellas áreas de la actividad médica en las que es especialmente difícil establecer el origen del daño por la acción (omisión) de un determinado trabajador médico, incluso para elementos individuales del régimen. Como resultado, el estudio presentado es relevante y significativo no solo para Rusia, sino también para otros Estados que aún no han desarrollado una regulación legal reglamentaria especial estable de estas relaciones.

Palabras clave:

Indemnización, culpa, daño, salud, responsabilidad, esquema.

I. Introduction

The problems of a medical error and the determination of its legal consequences undoubtedly occupy a significant place among urgent problems of Russian legal science. The reasons for this are the peculiarities of medical activities aimed at protecting one of the most important material benefits of a person, the presence of a significant amount of regulatory requirements for the quality of medical services, and finally, «narrowly corporate» protective nature of modern medicine and broad public discussion of individual, most egregious cases of harm to life and health. Opinions about the content of a medical error differ depending on the context and goals of a particular study. So, a medical error can be understood as a delusion of the attending physician regarding the performed medical manipulations, in which there are no signs of a criminal act in their actions (inaction),[1] conscientious delusion about the possibility «to prevent, to foresee the outcome of a particular medical action»,[2] failure to comply with professional standards.[3] Along with this, the existing doctrinal calculations, as a rule, are not used to substantiate various approaches to the legal regime of compensation for «medical harm» and are concentrated around discussions on toughening (mitigating) criminal liability for medical negligence.[4] Legislation in this area is still notable for the parsimony of special regulatory legal regulation.

In particular, article 98 of the Federal Law of November 21, 2011 No. 323-FZ «On the Fundamentals of Health Protection of Citizens in the Russian Federation»[5] actually repeats the norms of Ch. 59 of the Civil Code of the Russian Federation,[6] naming medical organizations and workers as responsible persons in arising tort legal relations, and referring to the general procedure for determining the volume and nature of harm to health. Despite the declaration in paragraph 7 of Part 1 of Art. 72 of the aforementioned law of the right of medical workers to insure the risk of their professional liability, such insurance is not compulsory (that is, it can be carried out at the expense of a medical organization or worker), it means that tort liability remains the main legal means by which full and fair compensation is ensured. The general conditions for the occurrence of such liability are also preserved, requiring the establishment of the unlawfulness of the action (inaction) of the inflictor of harm, the guilt in what happened, the onset of harm to health and the causal relationship between such harm and the actions (inaction) of a medical worker. The only exception to the general rule is related to the possibility of extending the provisions of article 1095 of the Civil Code of the Russian Federation in terms of the obligation to compensate, regardless of fault. At the same time, attention is

traditionally drawn to the fact that the effect of the rules on strict liability is limited to cases of «the presence of constructive, prescription or other deficiencies» of a medical service or the failure to provide sufficient information about it, it means that the provision of medical care and treatment is not mediated by an agreement for the provision of paid medical services, deprives the victim of the right to exclude guilt from the number of circumstances to be justified (Maria I. Kislaya & Alexey O. Kisly, 2020). This approach is also supported by judicial practice[7]. In all cases, regardless of the application of strict or general tort liability construction, the partial fault of the victim themselves for causing harm to health cannot entail a refusal to compensate, but can contribute to a proportional reduction in the amount of compensation (except for the costs of treatment and medical and social rehabilitation for Clause 1 of article 1085 of the Civil Code of the Russian Federation).

It should be noted that in world practice, the problem of medical error in a number of states has led to a more meaningful understanding of the issues of compensation for harm caused and contributed to the formation of special means of compensation, in the content of which traditional legal institutions, such as tort liability and insurance, have undergone significant modifications taking into account the specifics of medical activity risks, difficulties in determining the conditions for the onset of civil liability and the readiness of the state to take on part of the losses arising on the side of victims as a result of a medical error. Thus, a study conducted in 1991 by a team author at Harvard University showed that when adverse events in medicine are registered in 3.7% of all hospitalizations, only in 28% of cases there are signs of guilty failure or improper performance of their duties by medical personnel. It means that the majority of patients suffering from «medical injuries» are not eligible for compensation under the tort liability institute. Within the framework of the publication, as opposed to the concept of «medical error», the concept of «adverse effects of treatment» was proposed, which means the injury caused by medical intervention (and not the underlying disease), as a result of which the period of hospitalization was extended and disability was established. In the field of medical practice, under the guilty harm (medical error), the authors consider it is necessary to understand such treatment and patient care that does not meet the standards expected from doctors in society (Troyen A. Brennan *et al.*, 1991, p. 324).

To a large extent, under the influence of this doctrinal approach, special systems of compensation for harm caused in the process of medical activity were developed and proposed for practical application, based on a combination of the structure of tort liability and compensation schemes without fault, or on the use of the latter in a pure

form. They were based on the general hypothesis that damage to health in medicine is often caused by inevitable human error against the background of systemic failures and risks inherent in this area of human activity, *i.e.* that the cause of harm more often lies in «system errors» (the health care delivery system) rather than «human errors» (culpable violations by a particular health worker) (Jing Liu & David A. Hyman, 2020, p. 405, 419). The proposed theoretical justification remains relevant at the present time, and the use of the tort liability structure in its strict version is increasingly negatively assessed by its supporters as contributing to the development of «protective medicine», the essence of which is to carry out unnecessary diagnostic procedures in order to protect from possible lawsuits, denial of medical care in situations where the risks of an unfavorable outcome are high, as well as concealment of the facts of damage to health (Kelly Bookman & Richard D. Zane, 2020, p. 539, 545). Along with this, in each state, in view of the specifics of the organizational and legal support for the provision of medical care to citizens, its own combination of available legal means of compensation is being formed. So, in the Scandinavian countries priority was given to innocent schemes, which mainly use the institution of collective patient insurance, which does not exclude the subsidiary application of tort liability rules (only in Denmark, a patient does not have the right to go to court with a tort claim if the damage caused is fully covered by the compensation system without fault). In most European countries, China, Japan, the United States (the states of Florida, Virginia, etc.), such schemes are used selectively, for cases of harm as a result of specific medical procedures and manipulations (during vaccination, in relation to the field of obstetrics, etc.) (Vera Raposo, 2015, p. 942, 945), while the rest remains the classic structure of tort liability, based on evidence of negligence as an unlawful culpable violation of obligations to patients, defined by the contract or generally recognized standards of professional activity.

In general, it can be stated that discussions around the problem of a medical error have contributed to the formation of two types of special compensation schemes, which differ depending on the role assigned to the institution of tort liability in each of them. We are talking about schemes of compensation without fault, characterized by a complete or partial refusal to use this institution in parallel with the introduction of personal insurance for patients, and tort compensation schemes, which are distinguished by the preservation of the insurance, subject to the introduction of special legal presumptions relating to individual conditions for the liability occurrence. A comparative legal study of foreign experience in the application of these schemes represents a

significant potential for determining the prospects for the development of Russian legislation in the relevant part, which is the purpose of this study.

It is an attempt to summarize the main options for basic compensation schemes. In particular, as variations for the first type, the following are identified and analyzed: mixed schemes of compensation without fault, implementing the criterion of preventable injury (Scandinavian countries – Denmark, Norway, Sweden, Finland); mixed schemes of compensation without fault, based on the principle of equivalence of legal means of compensation (France and Belgium). As an alternative to innocent schemes, there are examples of justifying special legal presumptions for cases of medical error in states adhering to the concept of the fundamental role of tort liability in the system of legal means of compensation for harm caused by the action (inaction) of a medical worker, as well as attaching special importance to the deterrent function of tort law. The results of the study are presented below.

II. Compensation schemes without fault: main options and conditions for implementation

1. *Mixed Fault-Free Reimbursement Schemes Implementing Injury Preventability Criterion (Scandinavian Countries)*

Anticipating the consideration of the specific features of mixed schemes of compensation without fault, applicable to cases of medical errors in the Scandinavian countries, we emphasize that the general operation principle of absolutely all schemes of compensation without fault without exception is the exclusion or limitation of the rules on tort obligations in parallel with the introduction of the institution of insurance of risk of harm, as well as the establishment of the foundations of the legal status of «health courts», other administrative or arbitration bodies created specifically for the assessment and settlement of claims related to harm to health. For example, in Sweden all medical organizations and private practitioners are required to take out a comprehensive insurance that combines life and health insurance of patients and insurance of their professional liability. Two prerequisites are established for the payment of insurance compensation, namely: the preventability of injury, understood as the ability to avoid such injury, including through an equally effective, but fundamentally different medical procedure or treatment strategy, and the severity of the harm caused to health, determined according to formal criteria (at least 30 days of hospitalization or 10 days during which there is permanent disability). In the Swedish health care system, 17 district medical councils and 4 regional authorities are responsible for organizing the

provision of the necessary medical care to the population, which organize the financing of public hospitals and the purchase of medical services from private providers at the expense of the regional share of income tax. They also act as insurers in respect of property interests related to harm as a result of treatment, and the only insurer – the County Council Mutual Insurance Organization (Landstingens Ömsesidiga Försäkringsbolag, LÖF), guided in its activities by the Patient Injury Act 1996 (PIA 1996)[8] – considers all material claims of the affected patients. Comprehensive insurance acts as liability insurance when a tort claim is filed against an organization or a doctor.

The exclusion of the component of guilt from the list of conditions for the appointment of compensation does not mean that the subjective component has no legal significance in the investigated legal relationship. The rule of avoidability is a special criterion for determining subjective grounds for material claims, which, according to the most common doctrine approach, is regarded as a cross between the traditional criterion of guilt and the evidentiary standard of independence from it, adopted in the construction of strict liability (Andrew Roy & Nina Ross, 2020, p. 221). Compensation is awarded to patients with avoidable injuries under optimal conditions, insofar as they could be prevented by the efforts of an «experienced specialist» with the best special care. The «experienced specialist» standard, in turn, assumes that all the risks and benefits of various treatment options are considered retrospectively, based on the consequences that have occurred, however, for each case, it is taken into account that there are developed clinical protocols for the treatment of the disease during the period of medical service. In addition to preventable injuries, the insurance indemnity covers: material injuries as unavoidable damage to health caused by a defect or improper use of medical devices or hospital equipment, infectious injuries as cases of contracting an infectious disease from an external source during the provision of medical care, injuries caused by an accident, - as unavoidable injuries that occurred in exceptional circumstances during the treatment period (for example, as a result of a fire in a healthcare facility).

Determination of the amount of harm is carried out in accordance with the general rules for compensation for harm in the procedure of bringing to tort liability, set out in the Compensation Act 1972,[9] with the only procedural feature, which is that the consultants involved in evaluation of claims must have legal and medical education. At the same time, the basic principle remains the principle of full compensation, and the payments themselves cover material (loss of earnings (income), treatment costs – in the

part not covered or not provided by other types of insurance and social assistance) and moral damage (monetary value of pain and suffering, disability and related disabilities, permanent physical disfigurement, etcétera). The assessment of material damage is always carried out according to the actual costs (losses), and to determine the amount of compensation for moral damage, unified tables have been developed, the algorithm for applying which is based on knowledge of the type, severity of damage and the duration of treatment. We also note that the victim was granted the right to additional one-time compensation in the presence of persistent disorders of the body's functions, established as a percentage based on the results of a medical examination. There are no specific criteria for calculating it for medical injuries, and therefore tables created by the Association of Road Insurers are subject to application – here the payment amounts are indicated for a specific percentage of disability for each type of injury.[10]

State insurance systems for indemnification of damages, built by analogy with the Swedish one, exist in all Scandinavian countries. However, they have some differences in the conditions of application and the amount of compensation. In particular, in Finland, the category of insured events includes not only «medical injuries», the understanding of which is similar to that adopted in Sweden, and exceptions similar in meaning (nosocomial infection, injuries caused by the failure of medical equipment, etcétera), and so-called «unreasonable damage to health» – cases of deterioration of the patient's health, not associated with the course of the initially identified disease or exacerbation of chronic conditions.[11] Compensation of injury is determined by the observance of five prerequisites, including: 1) bodily harm received by the patient; 2) connection of health damage with the process of treatment or provision of medical care; 3) the condition of the victim in the status of a patient, *i.e.* a person undergoing medical examination or treatment; 4) getting injured during the period of the said law's duration; 5) the occurrence of the relevant event within the geographical territory of Finland. At the same time, insurance payments are made only for significant injuries, while the criterion of significance is complex – it is required to establish adverse consequences in the form of persistent limitation of life, irreversible aesthetic damage and/or incurring treatment costs in excess of 200 euros. The decision on compensation for harm is made by the Patient Insurance Center (Potilasvakuutuskeskus) in two stages: at the first, a conclusion on the compensability of the injury is prepared, at the second, the claims evaluators determine the amount of the payment based on objective data and additional information provided by the applicant (prescriptions, receipts for drugs and medical

services, documents on compensation and benefits provided under other insurance systems).

The amount of compensation in Finland is also determined in accordance with the general tort law and includes the costs of medical treatment and other necessary expenses caused by injury, compensation for temporary incapacity for work (until 2006, the corresponding amount was taken into account as part of moral damage), for permanent disruption of body functions (disability), for irreversible aesthetic damage, reimbursement of lost earnings (income), as well as, if there are grounds, reimbursement of costs for outside care services or reimbursement of lost earnings (income) in favor of close relatives of the victim who provide such services to them free of charge. When a victim files a tort claim, the Patient Insurance Center acts on behalf of the medical organization or doctor who is believed to have committed a medical error. However, such representation is of an exclusively procedural nature and is not associated with the obligation to compensate for the damage caused, since the Center does not provide professional liability insurance.

A distinctive feature of Denmark is the existence of two separate legal regimes for injury compensation for injuries caused by treatment (Patient Insurance Act)[12] and the use of drugs (Medicines Compensation Act).[13] The preventability rule and the «experienced practitioner» standard are also used to determine the relevance of health damage to the scheme, however, unlike in Sweden and Finland, the retrospective rule does not apply here. Compensation of injury is assessed according to the «rule of tolerance», which assumes the possibility of compensation for harm only for unusual or serious injuries that entail such permanent damage to health that could not be foreseen and rationally assumed, taking into account the severity of the underlying disease, the required course of treatment, the severity and likelihood of side effects. Like in Sweden, injuries resulting from the refusal or misuse of medical equipment are included into a separate category of insured events, but health damage due to accidents in health care facilities is considered in this capacity only if there is evidence of a guilty offense. The threshold requirements for the payment of insurance indemnity are based on the criterion of the significance of the amount of the claim (at least DKK 10,000 in total and at least DKK 1,000 in the case of dental injuries caused by private dentists), at the same time, such reimbursement includes the components of material and moral harm calculated in accordance with the general provisions of civil law.

The Norwegian Innocent Patient Compensation System, implemented by the public insurer (Norsk Pasientskadeerstatning, NPE), through the mandatory insurance premiums of healthcare organizations and municipalities, is characterized by the most emphasis on the subjective background of each case and the establishment of mixed eligibility criteria for a claim. The harm caused to the patient's health is subject to compensation, if: 1) it is a consequence of a medical error or omission (in fact, a guilty misconduct of a medical worker) that occurred in the process of medical examination (diagnosis), treatment and follow-up of the patient; 2) it is sufficiently serious and unforeseen, taking into account the assessment of the risks to which the patient had to agree in advance.[14] As you can see, not only the behavior of a medical worker is subject to legal assessment, but also of the patient themselves (for the latter, in terms of voluntarily assumed risks). As in other Scandinavian countries, Norway has a minimum amount of damage caused (at least NOK 5,000), but compensation can be awarded even if this threshold is not reached if the injury is irreversible and / or has resulted in permanent disability. The compensation includes reimbursement of lost earnings (income), treatment costs and the purchase of drugs, travel to the place of treatment and back, as well as additional compensation in case of permanent disability (at least 15%), the purpose of which does not depend on the availability or evidence of specific material losses. The filing of a standard tort claim is acceptable in cases not covered by the scheme, as well as if the victim incurs additional costs in the future.

In the examples, the innocent schemes are of a mixed nature due to attempts to take into account the subjective prerequisites for the occurrence of medical injuries (the criterion of preventable injury, the rule of tolerance and the standard of an experienced specialist), they are designed for a wide range of situations in which the patient's health is harmed. They are considered a priority legal remedy because tort claim is only allowed on the basis of subsidiarity and exclusivity. In rare cases, the legislator takes a different path, maintaining the tort and innocent regime of payments as independent subsystems, and each of them is designed for a specific type of unfavorable phenomena in the field of medicine, *i.e.* the mixed nature of the type of scheme under consideration is realized in conditions of equivalence of available legal means of compensation and providing the victim with an alternative to choose between them.

2. *Mixed schemes of compensation without fault, based on the principle of equivalence of legal means of compensation (France and Belgium)*

In France, the Code of Public Health provides for both a general construction of civil liability, accompanied by its compulsory insurance, and compensation without fault.[15] To make a claim within the framework of the compensation system without fault, it is necessary to reach a certain severity level of the damage to health (at least 24% of total disability) and agree to the consideration of the claim by a special administrative body - the Regional Commission for Settlement and Compensation (Commission Régionale de Conciliation et d'Indemnisation, CRCI). The no-fault redress scheme covers only «medical accidents» where the harm to health is an abnormal consequence of a medical procedure or treatment, provided that such consequences could be assessed and determined. The proposed alternative legal regime for compensation without fault - as noted in the doctrinal sources – is neither contractual nor tort in nature (Eldo E. Frezza, 2020, p. 89).

From a procedural point of view, the implementation of the right to compensation after the transfer of the case to the CRCI implies a comprehensive medical and legal assessment of the case for compliance with the criteria for the severity and urgency of the harm caused, based on the available information about the previous state of health of the victim and the predicted risks of the disease development. The decision on the legal regime of compensation is taken only after such an assessment, while in the case of the fault of the medical worker or the organization, payments are made by professional liability insurers, in the absence of fault - by the National Directorate for Compensation for Damage Caused by Health Accidents (National d'Indemnisation des Accidents Médicaux, ONIAM). In any case, patients retain the right to go to court with traditional tort claims, and insurers are given the right to challenge the basis for payments and the amount of compensation, as a result of which the entire scheme adopted for the consideration of claims for medical injuries in France is criticized as unnecessarily overloaded with additional administrative procedures (Lionel Collet, 2020, p. 598 y 600). In addition, attention is drawn to the lack of consistency in the interpretation of the term «medical accidents», which manifests itself in the fact that each situation is assessed by the CRCI individually, without an established understanding of the parameters of «foreseeability» and «extremeness» of the injury, as well as the «undesirability» of the consequences (Isabelle Parizot *et al.*, 2017, p. 99 y 105).

A similar scheme is used in Belgium, where the severity and abnormality of the damage to health opens up access to compensation from a specially created fund (Fund for Medical Accidents, FMA) (Kenneth Watson & Rob Kottenhagen, 2018, p. 1, 15). A significant difference here is that the creation of a special body for settling claims frees

the victim from the need to go to court and prove certain legal significant circumstances, the presence of which, as a general rule, is necessary for the appointment of compensation (including guilt and the amount of damage caused). However, the very content of these legally significant circumstances remains unchanged, as well as the structure of tort liability to be applied. Consequently, the Belgian scheme can be seen rather as a transitional type, but not as a redress without fault.

III. Tort compensation schemes: scope of special legal presumptions

1. *Rationale and content of special judicial-legal presumptions for cases of medical errors in Germany*

Having analyzed the systems of compensation without fault, let us dwell separately on the trends in the development of guarantees of legal protection of the patients' interests in states that have not developed special organizational and legal mechanisms for resolving material disputes with the participation of victims. One of the striking examples of such countries is Germany, where, according to the no-fault model, only compensations for harm caused by drugs are regulated,[16] and the strict liability rule is limited to the usual scope of product liability norms in European countries[17] (*i.e.* can only go about defective medical products). The legal basis for awarding compensation for harm caused to the patient's health as a result of a medical error remains Sect. 823 (1) BGB[18] on tort liability, in turn, negligence is considered among the conditions for the occurrence of such a refusal to exercise reasonable care, regardless of the risky nature and other features of the existence of the relevant legal relationship.

Of particular interest in the German legal system is the standard for establishing guilt in the form of negligence, which in its most general form implies that reasonable care is not considered to have been exercised if «a conscientious medical professional with average experience in the relevant field and a positive reputation» consciously and with understanding possible adverse consequences takes on tasks related to treatment, without having sufficient competence, solves such tasks contrary to the existing knowledge, standards and professional qualifications. A causal relationship is also essential for the satisfaction of a tort claim, which means that in each case of a guilty violation by a doctor of his official duties, the patient must confirm that the injury occurred precisely in view of the specified violation, and not as an inevitable consequence of the underlying disease. German law uses here the formula «conditio sine qua non»,

which limits liability to cases in which the delinquent's guilt cannot be «mentally removed» without the patient's trauma also ceasing to exist. In practical terms, this means that the physician's misconduct must be justified as a necessary condition for causing harm, which is generally straightforward, given that the injury usually occurs within the risk from which the physician was obliged to protect his patient. At the same time, some difficulties may arise when excluding accompanying risk factors, the complexity of which is a typical situation in medicine, from among the circumstances, each of which can serve as an independent actual cause of injury (Klaus Fischer, 2020, p. 516, 517). Their resolution is currently associated with the application of special evidentiary standards developed by German jurisprudence.

Among the most significant judicial and legal presumptions should be noted the presumption of «gross error in treatment» («grobe Behandlungsfehler» – German), which is informative in nature and suggests that a causal relationship is considered established if the treatment was especially careless and created more than negligible risk of injury in a particular situation. Specifying the concept of «gross error in treatment», the Federal Court of Germany notes that in order to fulfill this criterion, it is not enough to establish the fact of any violation by a doctor of his official duties, since such can be committed by a sufficiently prudent and conscientious specialist. It is not «subjectively unforgivable» violations that should be considered as a gross error, but such cases of non-performance or improper performance of official duties, which are manifestly unreasonable given the requirements for the level of professional training and qualifications that medical workers must have.[19]

In addition, a very special case of injury to a patient in Germany is considered to be an injury resulting from the failure of medical professionals to comply with the obligation to obtain informed consent from the patient. Regardless of the severity of the risk related to the treatment process, inadequate disclosure of information about it is treated as «unlawful bodily harm» according to Sec. 823 (1) BGB, which eliminates the need for additional justification of guilt and causality to satisfy a claim for damages. The jurisprudence maintains high standards of disclosure of information about the risks associated with the provision of medical services, focusing on the doctor's obligation to disclose all information available to them about the nature and purpose of treatment, its available risks and alternatives, as well as any other significant aspects of foreseeable risks, if these are related to treatment, they can affect the patient's consent to treatment or subsequently have any significant impact on the patient's lifestyle. In cases of this category, it is presumed that the treatment itself is an unlawful act due to the lack of legal

grounds for it, while trauma is the result of this offense. The only defensive argument for the doctor is the justification of the fact that if there was information about the controversial risk, the patient would still agree to treatment («hypothetical consent», or «hypothetische Einwilligung» – German), *i.e.* refusing treatment would objectively run counter to his interests.[20]

In order to compensate for the harm caused to the patient due to a medical error, Germany has a professional liability insurance («Haftpflichtversicherung»), and although the conclusion of an insurance contract is not considered a prerequisite for starting a medical practice, the health authorities strongly recommend this measure in order to protect against the risks of insolvency for both medical organizations and individual private practitioners. The amount of damage is calculated according to general rules and includes a material component based on financial losses («materielle Schdden»), and non-pecuniary damage, reflecting the monetary value of the patient's pain and suffering («immaterielle Schdden / Schmerzensgeld»). Material damage includes actually incurred and future costs of treatment, rehabilitation and outside care, costs of re-equipment of the house, lost earnings (income). Despite the voluntariness of professional liability insurance, the procedure for resolving disputes over medical injuries is distinguished by the existence of a special organizational and legal mechanism that makes it possible to achieve compensation without going to court. The main role in this mechanism is assigned to expert and arbitration commissions (Gutachterkommissionen und Schlichtungsstellen), subordinate to the state medical associations of the states (Landesdrztekammer), operating throughout Germany (Johannes Riedel, 2019, p. 294; Peter Glanzmann, 2021, p. 159). Contacting the association is free for the injured patient, and the procedure itself includes the preparation of a report on the nature and severity of health damage (carried out by an expert commission) and a medical-legal opinion on the existence of grounds for assigning responsibility to a doctor or a medical organization (prepared by an arbitration commission, which includes a lawyer). All conclusions are formulated on the basis of an analysis of the evidence agreed by the parties, at the same time, the final decision does not prevent the victim from going to court.

We see that the German approach to compensation for harm caused in the course of medical activity is characterized by a significant margin of appreciation of the courts, which allows the latter to develop judicial and legal presumptions that modify the traditional structure of tort liability in the interests of the victim. The result of such an approach may be excessive compensation, however, in the doctrine, such a development

of events is more often viewed as a permissible expression of corrective justice, carried out, inter alia, through the redistribution of losses in a democratic social state (Marc S. Stauch, 2011, p. 1149 y 1150). It should also not be forgotten that a significant part of the losses incurred by the victims is compensated in kind within the framework of compulsory health insurance and social security, as a result of which the question of the possibility of introducing special compensation systems in this area, built on the model of compensation without fault, is not is on the agenda of the legislator in Germany.

2. *Specific examples of the normative consolidation of special legal presumptions for cases of medical errors in selected countries*

In some jurisdictions, the normative consolidation of the concept of a medical error and its types has been adopted, while the detection of one or more of the listed violations allows us to consider the fact of a guilty violation of the legal obligation to provide medical assistance or treat a specific patient, as well as the causal relationship between the violation and the damage to health established. For example, in the UAE, a medical error is a violation committed by a practicing physician, which consists in: 1) ignorance of certain technical aspects of treatment, which should be known to any practicing specialist of the same specialization and level of training; 2) non-compliance with recognized professional (medical) standards; 3) lack of due diligence; 4) negligence and carelessness. It is allowed to specify the types of serious medical error in the sub-legal regulations[21]. In the United States, in most states (excluding the specialized compensation systems in Florida and Virginia), as opposed to proving a direct causal relationship, the patient only needs to demonstrate a sufficient relationship between a violation of professional standards and the injury that is the «immediate cause» of the injury (Bhajanjit Bal, 2009, p. 339, 344). In addition, in order to limit judicial discretion and speed up the trial, strict guidelines are used to calculate the amount of compensation, limiting its maximum amount: for the amount of all types of losses and expenses, including material and moral damage (states of Louisiana, Colorado, Indiana, Virginia), only for non-pecuniary damage (Florida, Hawaii, Idaho, Georgia), depending on the medical professional's form of guilt (Alaska, Maine, Maryland, Oregon, Wisconsin), depending on whether the medical services were provided by a public medical organization, a private clinic or a private practitioner (Colorado) (Meghana S. Chandra & Suresh B. Math, 2016, p. 21 y 25). India, Germany and Canada also have a standardized benefit, and the UK has experience with alternative legal mechanisms for dispute resolution with injured patients outside of Germany, where the National Health Service (NHS) implements a national program to protect against the risks of clinical

malpractice based on the voluntary participation of medical organizations and individual specialists in professional liability insurance (including ensuring the payment of life compensation to victims in the event of disability) (Thi B. Nguyen, 2019, p. 1, y 15).

It should be noted that referring to the example of other states that have retained the structure of tort liability as the main legal remedy for compensation for harm caused as a result of a medical error, suggests that the establishment of special legal presumptions is permissible in relation to any of the conditions for the occurrence of such liability. In other words, movement towards doctrinal justification and legislative consolidation of schemes of compensation without fault is seen here as far from the only alternative.

IV. Conclusions. Mixed compensation schemes - the way for Russia?

A critical analysis of the above systems suggests the ineffectiveness of «clean» compensation systems without fault in countries where there is a developed system of social security and health insurance, and claims about bringing a medical worker or organization to tort liability are mainly resolved with insurers of such liability. At the same time, implicitly, the main incentives for abandoning the tort liability structure are not the problems of proving guilt as such, but the inadequacy of such a structure to the specifics of medical activity and the lack of the practice of expert assessment of cases of medical error. The systems of compensation without fault, in addition to excluding such from the number of legally significant circumstances established for the recovery of compensation, are characterized by the separation of the purposes of compensation and punishment (the latter is implemented only within the framework of bringing a guilty medical worker of criminal and disciplinary liability), the introduction of criteria for compensating an injury and / or compensation for certain types of losses, the existence of special (insurance or budget) funds, on which the claim for compensation is transferred. The implementation of the institute of tort liability, on the contrary, is associated with a predominantly judicial procedure for resolving a dispute, the duration of consideration of a specific claim, which is especially important for severe injuries in view of the duration of the stabilization of the victim's health and the need for an objective assessment of persistent disorders of the body's functions, however, at the same time, it contains more flexible mechanisms of influence on the offender (deterrent effect) and presupposes the operation of the principle of full compensation in order to restore

the situation that existed before the violation of the law, retains the possibility of assigning punitive damages in jurisdictions where this institution is historically justified.

The criterion for the avoidance of injury introduced in mixed systems of compensation without fault (especially in the Scandinavian countries) deserves criticism as a disguised standard for defining guilt in the form of negligence. It acts with the only difference that when bringing to tort liability it is about assessing the behavior of a doctor as an average «reasonable person» who chooses the most reasonable treatment strategy under the current conditions, but not necessarily the best approach to providing medical care of all possible options or individual services. Indeed, avoiding harm means that adequate medical attention has not been provided by the health care provider or organization there was no due diligence and discretion in relation to the patient, the only difference is how to assess the necessary degree of «due diligence and discretion» – from the standpoint of a particular specialist or «the best in the profession». This confusion is confirmed by the example of Germany, where, while maintaining the traditional structure of tort liability, judicial practice justified the criterion for determining guilt in claims for medical negligence, arising from the assessment of the behavior of a medical worker from the position of «a conscientious doctor with average experience and a positive reputation». It should be assumed that for a true scheme of compensation without fault, the main criterion for compensating harm should be the origin of injury from the scope of risks inherent in medical activity. Mixed schemes using the criterion of avoidability can be confidently considered as transitional, applicable when the institution of tort liability is abandoned, but even before the proper doctrinal justification and legal support of the system of innocent compensation.

In general, the problem of compensation for harm to health caused as a result of a medical error is not focused on the compulsory insurance of the risk of professional liability in health care, although this is an important legal means to protect the material interests of doctors and patients. The study of foreign experience allows us to assert that the specificity of the risks inherent in the processes of medical care, diagnosis and treatment, necessitates the existence of special legal presumptions established in relation to certain conditions for the occurrence of such liability and thereby alleviating the situation of the victim.

In particular, it seems reasonable to establish a presumption of a gross error in treatment, the essence of which is the assumption of a causal relationship when one or more of the most significant violations of official duties by a medical professional is

detected. This category may include cases of gross violation or ignorance of medical standards, indicating the discrepancy of a specialist with the declared specialization or level of preparedness, unreasonable limitation of the scope of treatment or the list of diagnostic measures, failure to comply with the obligation to obtain the patient's informed consent for treatment. An exhaustive list of cases of gross violation of duties and (or) the most essential duties of a medical worker, the violation of which will be interpreted as gross, should be consolidated after consultation with the medical community in article 73 of the Federal Law «On the Fundamentals of Health Protection of Citizens in the Russian Federation», with the extension to them of the rules on compensation for harm regardless of fault (the possibility of establishing such special cases is directly provided for by paragraph 2 of article 1064 of the Civil Code of the Russian Federation). This step will eliminate the contradiction arising from the application of article 1095 of the Civil Code of the Russian Federation, which consists in differentiating the rights of the victim depending on whether medical care is provided under a contract for the provision of paid medical services or free of charge (including under the compulsory medical insurance program), is obvious if we take into account that the risky nature of medical activities is inherent in its very nature, and not in the prerequisites for the emergence of legal relations between the doctor and the patient. In the given conditions, it is important to preserve the rule on compensation only for those types of losses that are not compensated in kind within the framework of compulsory medical and social insurance, which will ensure a balance between simplified conditions for compensation for harm and fair compensation.

Along with all that has been said, the prospect of introducing in the Russian conditions certain elements of compensation schemes without fault, especially for «accidents» in certain areas of medical activity, where determining the origin of harm from the actions (inaction) of a particular medical worker is especially difficult, and the outcome of a particular manipulation is influenced by a significant number of random and/or poorly understood factors (HIV infection during blood transfusion, the consequences of vaccination, neurological abnormalities as consequences of fetal hypoxia during childbirth). Regardless of the adoption of fundamental decisions in the field of creating additional insurance guarantees for compensation for harm caused in the course of treatment, an important element of foreign no-fault schemes recommended for borrowing is a system of independent expert assessment of cases of medical error operating outside the state health care system. The use of such a system, however, should be aimed only at determining the causes and conditions of harm to health, but not the

volume and nature of such harm. When establishing the latter, one should be guided by the general rules of Ch. 59 of the Civil Code of the Russian Federation in order to ensure the possibility of offsetting and the implementation by insurers of the risks of professional liability and risks of causing harm, reverse claims for uniform costs to insurers for social types of insurance.

The distribution of various types of losses between the participants of the compensation scheme must be done in such a way that the initial and urgent costs are reimbursed in a simplified manner, preferably by professional liability or harm risk insurers, and periodic payments and forecasted costs of medical and social rehabilitation for the future are reimbursed by the person responsible for such harm, according to Ch. 59 of the Civil Code of the Russian Federation. When reimbursing treatment costs, priority should be given to compensation in kind, and an effective option for settling claims for reimbursement of lost earnings (income) may be the appointment of a lump sum insurance payment to compensate for the loss of general disability made without confirmation of the amount of earnings (income) before injury. This type of compensation will ensure the minimum compensation for the partially or completely lost ability of the victim to generate income. At the same time, it will reduce the burden on the courts and insurers due to the refusal of a significant number of patients from claiming periodic payments for the entire period of permanent disability.

V. References

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[1] Such an approach is found in the works of specialists in criminal law, seeking to delimit the term «medical negligence» from related concepts (Hippolyte V. Davydovsky, 1941, p. 3; Anatolij M. Bagmet & Lyudmila I. Cherkasova, 2015, p. 15-17; Anton V. Bykov & Denis Yu. Zemlyanskiy, 2020, p. 33).

[2] This opinion is typical for studies that substantiate the special, risky, nature of medical activity and the need for professional liability insurance (Aleksandr A. Mokhov, 2020, p. 12-18; Andrey P. Zgonnikov & Anna N. Pushkareva, 2015, p. 48).

[3] In such a narrow sense, a medical error is considered, as a rule, in relation to particular cases of improper provision of medical services (Irina V. Svechnikova, 2020, p. 32-37).

[4] Studies of this kind are especially numerous (Tural A. Kuli-Zade, 2019, p. 42; Svetlana I. Pospelova, 2020, p. 14; Arseny A. Bimbinov, 2019, p. 4-10),

[5] Russian Federation Collection of Legislation 2011, No. 48, Item 6724.

[6] Civil Code ch. 59.

[7] Appeal ruling of the Sverdlovsk Regional Court of the Russian Federation of 22 September 2020 No. 33-11370/2020, disponible en: *http://www.consultant.ru/cons/cgi/online.cgi?req=doc&base=SOUR&n=261251#08861604083898194*; Appeal ruling of the Moscow City Court of the Russian Federation of 26 November 2019 No. 33-48439 / 2019, disponible en: http://www.consultant.ru/cons/cgi/online.cgi?req=doc&base=SOCN&n=1220623#04162993922820244.

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[16] Arzneimittelgesetz, § 84, disponible en: *https://www.gesetze-im-internet.de/amg_1976/*.

[17] Produkthaftungsgesetz, §§ 1, 8, disponible en: *https://www.gesetze-im-internet.de/prodhaftg/*.

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