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ARTÍCULO DE INVESTIGACIÓN

# Socializar la responsabilidad civil de una organización médica por causar daños a la salud/DOI: 10.5281/zenodo.7812180

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**Resumen**

Durante muchos siglos, la responsabilidad civil en el sistema jurídico romano-germánico se basó en el principio de responsabilidad individual, según el cual debe establecerse una relación de causa-efecto entre el delincuente y el daño causado, así como en el principio de culpabilidad del causante del daño. Al mismo tiempo, el desarrollo de la ciencia y la tecnología, incluida la medicina, determina la aparición de un daño diferido en el tiempo y el perjuicio causado a los descendientes, lo que implica la culpabilidad implícita del delincuente. En estas condiciones, es necesario discutir la socialización de los principios básicos de la responsabilización del autor del daño. El tema se divulga utilizando métodos científicos generales (análisis sistémico, teórico e histórico) y métodos científicos especiales (derecho comparado, análisis lógico, técnico y jurídico, especificación e interpretación). El estudio pretende identificar la naturaleza teórica y práctica de la exigencia de responsabilidad a las empresas farmacéuticas y a las organizaciones que utilizan las nuevas tecnologías genéticas por los daños a la salud que hayan causado. También es necesario explorar la posible socialización de la responsabilidad civil por daños a la salud. El artículo examina algunos principios de la responsabilidad civil individual por los daños causados a la salud humana por los productos farmacéuticos y las tecnologías genéticas. Se concluye que los principios de exigencia de responsabilidad por daños a la salud deben modificarse, considerando la socialización de dicha responsabilidad.

**Palabras clave:** responsabilidad civil individual, socialización de la responsabilidad civil, causante de daños, daños a la salud, culpabilidad.

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**Abstract**

**Socializing the civil liability of a medical organization for causing harm to health**

For many centuries, civil liability in the Romano-Germanic system of law was based on the principle of individual liability, according to which a cause-and-effect relationship between a delinquent and the damage done must be established, as well as on the principle of guilt of an offender. At the same time, the development of science and technology, including medicine, determines the onset of harm delayed for a long time and the harm caused to descendants, implying the implicit guilt of the delinquent. Under these conditions, it is necessary to discuss the socialization of the basic principles of the offender responsibility. The topic is disclosed using general scientific methods (systemic, theoretical, and historical analysis) and special scientific methods (comparative law, logical, technical, and legal analysis, specification, and interpretation). The study aims at identifying the theoretical and practical nature of bringing pharmaceutical companies and organizations using new genetic technologies to responsibility for the harm to health they caused. It is also necessary to explore the possible socialization of civil liability for harm to health. The article considers some principles of individual civil liability for the harm caused to human health by pharmaceuticals and genetic technologies. It is concluded the principles of bringing responsibility for harm to health should be changed, considering the socialization of such responsibility.

**Keywords:** individual civil liability, the socialization of civil liability, offender, harm to health, guilt.

## 1.- Introduction

The principle of individual civil liability adopted by Romano-Germanic law from the Roman law is based on the following construction: "a specific delinquent – specific harm – a specific victim". This legal structure has been used in holding a subject of law liable

for more than a millennium. However, the world has entered the postgenomic era in the 21st century. Progress in the field of genome editing with the help of new pharmaceuticals or new genetic technologies has a positive effect in the form of a cure for many previously incurable diseases but also has a negative impact on human health and descendants, which causes the discussion about changing methods and forms of protecting human rights, including the right to health. The principles of bringing to civil liability developed by legal science several centuries ago cannot ensure a balance of interests between parties to legal relations or protect the rights of the delinquent and the injured party in the event of harm to the latter's health.

The current level of development of science in the field of biotechnologies and genetic technologies contributes to the emergence of fundamentally new pharmaceuticals for the treatment of rare diseases. The COVID-19 pandemic also accelerated the testing of such drugs for the treatment and prevention of a new disease that could inflict harm to health, including the health of a person's descendants.

In the Russian doctrine, most research is concerned not with the socialization of the tortfeasor's responsibility but with the conditions for exempting a medical organization from liability for the harm caused to the patient's health, if these harmful consequences were an act of force majeure. In Europe and the United States, a different approach has been developed to bring a pharmaceutical company or medical organization to civil liability for harm to health.

## 2.- Methods

Throughout the research, we used general scientific methods, including the principle of objectivity and consistency and theoretical and historical analysis. We also applied special scientific methods: comparative law, logical and technical-legal analysis, and specification. The methodological basis of the study was the theory of cognition.

## 3.- Results

Indeed, most new pharmaceuticals aim at improving the quality of human life and curing genomic and other intractable diseases. For example, the recombinant DNA technology developed by US scientist Paul Berg in 1972 was used to construct the recombinant DNA containing the INS gene. Without long-term testing, new genetic technologies and new drugs based on a program (code) can pose a threat to the life and health of the next generations since they edit the human genome and, ultimately, change the biological patterns of hereditary transmission.

Genetic diagnostic tools allow one to examine the genome of a particular person, decode it, find broken genes, and fix them. At first glance, it seems to be simple. However, the human genome consists of 3.1 billion base pairs, forming 25,000 genes located on 23 pairs of chromosomes. Modern methods of treatment cut out a defective section in a broken chain of more than 3 billion nucleotides and replace it with a section

of nucleotides without a defect. There is a danger of cutting out not a defective but a healthy section of one's DNA. As a result, the next generations will inherit genomic diseases. In such a situation, questions certainly arise about who and to what extent should be responsible for causing harm to human health and their offspring.

In Russia, the use of genetic technologies does not have sufficient legal regulation, i.e. the law does not establish liability for their misuse and the risks of use are not assessed, which creates a wide field for possible abuse by unscrupulous medical workers. In this connection, A.Yu. Sokolov and N.V. Bogatyreva (2020) claimed that the state should play a major role in the system of social control to determine the risks inherent in the use of genomic technologies. However, each country has its system of control over new pharmaceuticals, drugs, and genetic technologies. In the US, professional associations of large corporations involved in the development of new technologies have more control. Since such control is exercised by private companies, when harm is done, the court places the responsibility on private companies. In Russia, control is assigned to the state and it would be logical to hold the state responsible for the harm caused to human health since it exercises not only control over the release of new drugs but also regulate the circulation of such drugs. This reveals one aspect of socialized civil liability for harm caused to human health as a result of exposure to new genetic drugs.

The possibility of compensation for harm to a citizen's health due to the use of medicines is enshrined in Article 69 of the Law of April 12, 2010 No. 61-FZ "On the Circulation of Medicines", according to which the right to compensation for harm is postulated only for persons who have suffered harm to their health, but not life. Thus, only a person whose health was harmed during the use of medicines can be a plaintiff in civil proceedings. Their offspring are deprived of the right to appeal to the court.

When considering cases in the court, the question will certainly arise about what is meant by the human health category and how to interpret the construct of causing harm to health. According to M.N. Maleina (2014), health as an intangible good should be understood as a certain physical and mental state of a person characterized by the absence of diseases or pathologies associated with the loss, psychological, physiological, anatomical disorders, and/or functions of the human body. Therefore, harm to health should be regarded as a violation of anatomy, integrity, physiological functions, and psychological and mental disorders and diseases. The consequence of causing harm to health will be the development of a disease or exacerbation of an existing disease, pathological process, trauma, tissue necrosis, etc. It seems that harm to health should be considered not only in relation to a person who took new drugs but also to their descendants.

Litigation should distinguish between the state of health of a person before the use of pharmaceuticals and the state of health after the use of drugs. However, we cannot observe physiological changes in the body (physiological changes) with the naked eye since these processes are hidden. In all cases of inflicting harm to human health, it is necessary to conduct a forensic medical examination. Such an examination should be

carried out by a special board consisting of the most experienced forensic doctors and clinicians.

It is also necessary to dwell on the epistemological essence of the concept of pharmaceutical products. According to Law No. 61-FZ "On the Circulation of Medicines", a pharmaceutical product is understood as a pharmaceutical substance of a recombinant nucleic acid, consisting of a cell line and excipients that passed the state registration as a product for medical use and allowing for the regulation, repair, replacement, addition, or removal of a genetic sequence. Based on the analysis of the above-mentioned laws, it should be concluded that a medical device that does not consist of a cell line but embodies methods and techniques for influencing the human body is a technology rather than a pharmaceutical product.

In cases of compensation for harm to human health caused by pharmaceutical products, the main problem is the concentration of evidence. To date, there are practically no scientific studies on the concentration of evidence in cases of compensation for harm caused by new pharmaceutical products. Consequently, the issues of searching, concentrating, and evaluating evidence require special research. In such cases, evidence-based work differs from evidence-based work in ordinary medical cases.

Based on the analysis of judicial practice in ordinary medical cases, the court should establish the following circumstances for the correct consideration and resolution of cases:

a) To determine the harm caused to human health;

b) To identify the subject who injured someone's health;

c) To establish a cause-and-effect relationship between the harm and the action of the harm-doer;

d) To prove the guilt of the perpetrator.

In ordinary medical cases, the court uses the principle of individual responsibility focused on by the Constitutional Court of the Russian Federation in Resolution No. 28-P of December 13, 2016 (Constitutional Court of the Russian Federation, 2016). However, this principle is not applicable in cases of compensation for harm to health caused by pharmaceuticals or genetic technologies, when it is necessary to proceed from the principle of socialized liability of all drug manufacturers since it is not possible to identify a specific manufacturer. The principle of individual liability in such cases will make it impossible to compensate for harm to human health since individual liability is eroded in a group and the existence of civil liability is called into question. P. Jourdain, Honorary Professor of the University of Paris 1 Pantheon-Sorbonne, drew attention to the crisis of individual civil liability and emphasized that the latest changes in civil liability revealed deep problems within the institution. Laws should adapt to the transformation of society and the new requirements for compensation for harm, which requires a revision of the foundation of responsibility and the common role of guilt (Jourdain, 2021).

The cases of harm to health caused by pharmaceuticals or genetic technologies should be divided into three types:

1) Cases where harm is inflicted on a patient taking a certain drug. For example, as a result of an incorrect diagnosis or an incorrect dose assigned by an attending physician, i.e. off-label use or the use of the drug outside the instructions. Most often, such cases are explained by the doctor's ignorance. However, there are other cases of off-label use caused by the incorrect promotion of drugs by pharmaceutical companies (Starchenko, 2021). According to A.V. Kuzmina, it is necessary to distinguish between such constructs as an error in the use of the drug and incorrect use of the drug. "An error in the use is the result of unintentional actions, while incorrect use is the intentionally inappropriate use of the drug" (Kuzmina, 2016: 76). In such cases, it is necessary to establish a cause-and-effect relationship between harm to health and the actions of the doctor.

2) Cases when harm is caused by medical products with the correct prescription and use. In such cases, either a pharmacy or a pharmaceutical company can be sued in conformity with consumer protection law. Under the current practice, it is presumed that a medical product meets the established requirements and is guaranteed by a special procedure for introducing this drug into circulation until proven otherwise. In these cases, only an examination can confirm a low-quality drug and its effect on the patient's health, as well as a cause-and-effect relationship between them. However, conducting an examination and drawing accurate conclusions is challenging since it is difficult to distinguish between the side effects of a drug and the symptoms of a disease. In addition, the doctor can prescribe several medications at once during treatment and harm can be caused by a complex of drugs.

3) Cases when harm to health is inflicted not on the patient, but on their offspring (the so-called "delayed harm to health"). There are no such cases in Russia but they can be found in Europe and the US (especially in recent years). For this category of cases, it is necessary to develop a different standard of proof and rules for assessing evidence since the general rules cannot be applied because a certain drug is produced not by one but by several pharmaceutical companies and it is almost impossible to establish a specific subject of pharmacological activity that was guilty of causing harm to the health of a citizen. As a result, the standard of proof should differ from the standard of proof in ordinary civil cases, including in cases of injury not related to pharmaceuticals.

In addition to civil liability for harm to health caused by drugs, harm to human health can also be caused by the use of certain genetic technologies. The treatment of a patient with the help of new genetic technologies might not always have a positive effect, depending on the subject using this or that technology. Any genetic technology has certain risks for human health, therefore the law "On State Regulation in the Field of Genetic Engineering Activities" distinguishes four levels of risks to human health. The Decree of the President of the Russian Federation "On the Development of Genetic Technology in the Russian Federation" also refers to the risks of uncontrolled distribution and use of genetic technologies. Based on the foregoing, it can be concluded that genetic

technologies have several features inherent in a source of increased danger since such activities are not controlled by human beings.

A.V. Pekshev (2021) claimed that the results of medical care could not be predicted due to high risks and described relationships between the patient and the medical organization as aleatory relations. However, not all medical care is unpredictable, therefore it is not acceptable to consider the relationship between the person taking drugs and the pharmaceutical company as an aleatory relationship with the transfer of risks to the patient or their offspring. The consent of a person to the voluntary use of medical products or the use of genetic technologies should not be the basis for exempting entities using genetic technologies or manufacturing pharmaceutical products from liability.

Since there are practically no technical regulations for the use of genetic technologies that would minimize the risks to human life and health, the court should regard such harm as harm caused by a source of increased danger with all the ensuing consequences. It is no coincidence that the relevant literature indicates that medical activity has a risky nature due to the complexity of the technologies used and the human factor. Thus, responsibility for the risk should be assigned to the provider of such services based on the risk itself rather than based on guilt (Svirin et al., 2017).

It is also unacceptable in a court session on cases of causing harm to health by pharmaceuticals or genetic technologies to establish a cause-and-effect relationship between a delinquent and a person. It means that law should establish a cause-and-effect relationship between harm and a drug or genetic technology until the opposite is proven. Such a rule should become the standard of proof in these cases. In France and Germany, a cause-and-effect relationship is presumed and not proven in pharmaceutical injury cases. In ordinary medical cases, the establishment of a cause-and-effect relationship is mandatory to bring a doctor or medical organization to civil liability.

In Russia, there are no prerequisites for conducting forensic examinations in civil cases related to genetic technologies and causing harm to health by such technologies. Genetic examinations are used to identify the DNA of the criminal or victim (the so-called genomic fingerprinting) only in criminal cases. Other countries have a similar situation with genetic expertise, including the US, even though genetic technologies are most developed and widespread there.

In legal proceedings, the process of proof aims at establishing facts of different significance. To designate the entire set of facts to be proven, the doctrine uses such a term as “limits of proof”. To determine the subject of proof and the limits of proof in a civil case means to give the entire process of collecting, researching, and evaluating evidence the right direction.

It seems that the subject of proof should be determined depending on the category of the dispute. Thus, there are different subjects of proof in cases, for example, about causing harm to health by surgical intervention and harm caused by pharmaceuticals or genetic technologies. Since it is almost impossible to establish the actual delinquent in cases of harm to health by drugs, the subject of proof should only include the harm

caused by a specific drug rather than by a specific delinquent. In ordinary medical cases, it is imperative to establish a cause-and-effect relationship between the harm done and the tortfeasor.

The fact of causing harm by a pharmaceutical company must be presumed by law. Along with individual (subjective) liability, there might be an objective liability for risk directly related to the socialized concept of law. In common law, there is a vicarious liability for risks, when guilt is not proved in a trial and all possible tortfeasors are held liable. Thus, a collective or indefinite delinquent fundamentally challenged the requirement of individual causality in tort law. In one of the cases, the victim was harmed because her mother, being pregnant, took pills containing the DES substance, which later turned out to be harmful to the embryo. Subsequently, the daughter filed a lawsuit against several companies out of 300 firms that produced drugs containing the substance. The victim was unable to prove which drugs her mother had been taking for many years before her pregnancy. Thus, there was no evidence of the individual causality of the actions of a particular delinquent which had adverse consequences for a particular victim and no specific tortfeasor among the defendants. However, the California Supreme Court ruled in favor of the victim. The court indicated that the defendants collectively represented a major market share and the harmful drug could be produced by one of them. If the defendants were unable to refute this assumption, then each of them could be held liable for the harm caused to the health of the victim in the amount equal to the share of each respondent in the market for this product. When making this decision, the US court for the first time departed from the principle of individual liability and constructed a legal structure of socialized liability of all possible harm-doers, in which the responsibility was assigned not to a specific harm-doer but to all possible harm-doers for the very fact of releasing dangerous goods that could harm the victim. The court did not establish a cause-and-effect relationship between the harm inflicted and the tortfeasor. This judicial precedent in Anglo-Saxon law called into question the principle of individual causality and gave rise to a serious scientific discussion about the legal nature of this civilistic phenomenon.

Organizations using genetic technologies or producing pharmaceuticals should be aware of the risk of inflicting harm on human health. Therefore, they should be held liable for the very fact of creating a risk or participating in hazardous activities. In this regard, D.E. Bogdanova (2012) highlighted that the idea of evidence-based grouping was closely related to the socialization of civil liability.

In Russia, the civil law doctrine is traditionally based on the postulate that a victim should prove that a delinquent harmed them by actions. In other words, a cause-and-effect relationship must be established between harm and a certain delinquent. However, the socialization of civil law and the strengthening of the principles of justice in the sphere of responsibility change scientific and judicial approaches regarding compensation for the harm caused by pharmaceuticals.

According to Yu.A. Svirin, a pharmaceutical company or a medical organization that opposes evidence-based activities must bear the risk of adverse consequences. If it

evades the examination and fails to provide the experts with the necessary materials and documents, the court must recognize the fact that needed clarification in the course of the examination as established (Svirin, 2023).

When resolving disputes about compensation for the harm to health done by pharmaceutical companies or medical organizations, the plaintiff refers to the defendant's guilt but is not obliged to prove it, as follows from the general rule of proof. The private rule should change the general rule on the distribution of proving duties, namely: the tortfeasor is obliged to prove that the harm was caused through no their fault. The tortfeasor's guilt is presumed by the rule of law. Moreover, the presumption of guilt should apply to all the circumstances arising from the fact of causing harm to health.

On the one hand, the issue of presumption is directly resolved by the legislator in favor of the victim who does not need to prove the guilt of the medical organization that caused harm to health in the course of providing medical services. In addition, Article 1064 of the Civil Code of the Russian Federation establishes a presumption of guilt of the tortfeasor. Under the interpretation of this norm, the defendant (not the plaintiff) shall prove their innocence. However, Federal Law of November 21, 2011 No. 323-FZ "On the Basics of Health Protection of Citizens in the Russian Federation" did not enshrine the right to compensate for the harm caused to a person during the provision of medical care or the harm caused by pharmaceuticals. This information is not covered in Federal Law of April 12, 2010 No. 61-FZ "On the Circulation of Medicines". According to Clause 3 of Article 68 of this law, the harm caused to the health of citizens as a result of the use of drugs or the commission of illegal actions by pharmaceutical companies is compensated in accordance with the legislation of the Russian Federation. In this connection, relevant questions are raised in the scientific literature: speaking about the lawful actions of medical workers, what are legal norms to compensate for harm to health? Is compensation for harm to health acceptable in this case at all?

In one of the cases about the dangers of the chicken plague vaccine in Germany, the plaintiff believed that the vaccine supplied by the defendant's company turned out to be defective. After vaccination, the plaintiff's chickens died. The emergence of the virus remained unclear and the court placed the risk of not proving another cause of harm on the defendant based on the fact that the main reason under investigation is related to the production process. According to the court, the defendant as a manufacturer can explain the relevant factual circumstances better than the plaintiff. The former controls the production and supply of finished products and determines and organizes the relevant technical processes (Markesinis & Unberath, 2002). Unfortunately, Russian courts for the most part refuse to satisfy similar claims, accepting documents on the quality control measures applied in production as evidence of the defendant's innocence.

The analysis of judicial practice demonstrates that disputes on compensation for harm to health when using genetic technologies are more often resolved in favor of pharmaceutical companies or organizations using genetic technologies. In addition, there is no uniform assessment of the evidence in this category of disputes. In one of

the cases, the defendant referred to the fact that all manufactured products were tested in an independent laboratory and periodically controlled in other laboratories. The evidence presented by the defendant was sufficient for the court to dismiss the claim, even though such control did not exclude the presence of foreign substances in the goods, including after passing the control, until the sale of the goods to the end consumer.

In our opinion, the socialization of civil liability should not lead to retributive justice. A tort in the field of causing harm to health should become a sphere of private, social, or even public interests, therefore the state should enshrine specific tools for protecting the violated rights in conditions where the generally accepted principles of prosecution do not work and do not provide adequate protection for the injured party.

## 4.- Conclusion

Based on the foregoing, we have drawn the following conclusions:

1. At the present stage civil liability should not be regarded as a monofunctional legal phenomenon correlated with corrective justice. The socialization of law implies the socialization of responsibility aimed not only at compensation for damage but also at a fair distribution of adverse consequences among harm-doers when it is impossible to prove the guilt of a particular delinquent.

2. The civilistic doctrine presumes a general rule, according to which the absence of guilt of a particular tortfeasor in causing harm exempts them from liability. However, if harm to health was caused by pharmaceuticals or genetic technologies, it is not required to prove the guilt of a certain delinquent since the principle of socialized liability of pharmaceutical companies should apply in case of harm to health.

3. Organizations using genetic technologies should be considered a source of increased danger with all the ensuing consequences.

4. In cases of harm to human health caused by pharmaceuticals or genetic technologies, the standard of proof must be changed. A pharmaceutical company or an organization using genetic technologies shall prove that the harm was not their fault since their fault must be presumed.

5. In cases of infliction of harm to human health by pharmaceutical preparations, a cause-and-effect relationship between the tortfeasor and the ensuing consequences should not be proved.

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