
Production of Biomedical Cell Products in the Russian Federation

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Abstract

The donation of biological material in the era of the scientific and technological revolution becomes the essential problem for legal regulation due to the need to ensure the biogenetic safety of man. Current Russian legislation lacks a clear mechanism for protecting the rights of the donor and the recipient, in connection with which it seems necessary to strike a balance between the donor's constitutional right to privacy and his right to information, on the one hand, and the recipient's right to health, on the another hand. The special legal significance of the issue is related to the problems of the application of laws such as the Federal Law of June 23, 2016 No. 180 "On Biomedical Cell Products", the Federal Law of 20.07.2012 N 125 "On Donation of Blood and Its Components". The article analyzes the legal regime for the provision of biological material for the production of a biomedical cell product (BMCP). The need for legal regulation of the protection of the rights of the parties when using BMCP is noted. The research results are based on the use of comparative legal, system-structural and formal-legal methods.

Keywords

Human Rights, Highest Value, Right to Privacy, Confidentiality, Legal Regulation, Biomedical Cell Product, Donor, Recipient.

Introduction

The progress of science and technology inevitably affected the methods and methods of treating and preventing human diseases. One hundred years have not passed since the discovery of penicillin, and today's medicine has reached previously unimaginable heights. The most striking example is the use in medicine of cell and genomic technologies that allow medical intervention using human cells with a certain degree of modification - biomedical cell products (hereinafter - BMCP). However, the rapid development of research in this area and the application of the results of such research in practice is fraught with many dangers, primarily in the field of protecting human rights. This is due to the fact that now the cells can be torn away from their carrier for subsequent processing, storage and use, become the object of influence and themselves act as active substances. In other words, there is a paradigm shift in the interaction of man and technology, a philosophical rethinking of the biological essence of man and a social revolution in the healthcare system. Against the background of these processes, it is necessary to ensure the maximum level of protection of human rights and freedoms, if necessary, revise existing approaches to legal regulation, always focusing on one of the main tenets of modern law - a person, his rights and freedoms are the highest value. The most vulnerable subjects in the application of cell technologies are the donor - the person who provides his biological material for research and the creation of cell products, and the recipient - the person for whom the created product is ultimately intended.

Methods

The method of comparative legal analysis revealed the distinctive features of organ donation, blood and its components and biological material for the production of BMCP.

The use of the system-structural method of cognition allowed the authors to formulate a list of the basic donor's rights.

The formal legal research method was used to determine the content of such concepts as "biomedical cell product", "biological material", "protection of human rights".

Results

Legal regulation of the donation of biological material is necessary for the proper handling of BMCP. The start of the BMCP life cycle is to obtain the biological material of persons who are ready to provide it voluntarily and free of charge. In this context, a person's right to protection of health, the right to privacy, the right to information that is worthy of the body of the deceased, the freedom of expression of agreement / disagreement to provide from one's body the basis for future BMCP receive special refraction and interpretation. Achieving a balance of interests is possible in the case of comprehensive protection of these rights, the formation of a legal culture in the application of biomedical technologies both from donors and recipients, and from research institutes, medical organizations and

government bodies. For this purpose, it is necessary to unify the current legislation, fill in the gaps in the legal regulation, bring the norms of civil and constitutional law into line with modern realities.

Discussions

Donation has a rather long and extensive history. For more than 200 years, a blood transfusion has been carried out (first made in 1795), in the 60s of the XX century, an organ transplant was performed for the first time. During this time, many countries have developed their own regulatory framework that regulates not only the procedure itself, however also the rights and obligations of its participants, the responsibility of medical employees, and the insurance system.

The main difference between biomedical cell products and medicines and medical devices is that they are based on human cells. The safest way is to use a person's own cells, since the immune response will not be as aggressive as in the case of the introduction of cells foreign to the body. However, autologous donation is not always possible due to diseases, conditions of the patient, the suitability of his cells for creation of BMCP. In this regard, Federal Law of June 23, 2016 No. 180 "On Biomedical Cell Products" allows allogeneic donation, that is, the use of one person's cell line for other individuals. To create BMCP biological material is taken. Biological material is understood as "biological fluids, tissues, cells, secrets and human waste products, physiological and pathological secretions, smears, scrapings, swabs, biopsy material" [1]. The donation of biological material is divided into in vivo and posthumous. Common to these species is that the production of biological material is possible only in organizations that have a license for medical activity on the basis of an agreement between such an organization and the manufacturer of BMC. Obtaining biological material is carried out not only for the production of BMP, but also for all the stages preceding it: a medical examination of the donor to identify contraindications, preclinical and clinical studies.

It should be noted that despite the common goal of organ and tissue transplantation and the production of BMCP, the legislation in these areas is not uniform [2]. A common link for both is a ban on the sale of organs and tissues / a ban on the sale of biomaterial [1], which is explained not only by legal, but also by ethical doctrine. However, the main provisions of the two laws are unmotivated diverging: the law on transplantation, the law establishes the "presumption of consent" for the removal of organs and (or) tissues, and the law on BMCP - "the presumption of the absence of consent".

A certain systematization and detailing is required by the human rights protection system in the implementation of biomaterial donation. In our opinion, it is necessary to focus on the following list of rights: (1) the right to protection of health, (2) the right to privacy, (3) the right to information (4) the right to respect for the body of the donor after his death.

Undoubtedly, the basic right in this list is (1) the right to health protection[3]. The collection of biological material for the production of BMCP is a procedure associated with exposure to the body, and therefore must be carried out in accordance with the rules for the production of biological material, which are enshrined in Order of the Ministry of Health of the Russian Federation of 08.28.2017 N 569: obtaining biological material from of the donor is carried out by "specialist doctors and (or) medical employees having professional (medical) education. At the same time, all sanitary and hygienic requirements must be observed in order to prevent infection and other adverse effects.

Next, it is important to focus on (2) the right to privacy [4], the importance of which is sometimes not obvious. It should be understood that cells are valuable not only in themselves, as a certain object for intervention and use, but also as carriers of the genetic material of their owner. Each somatic human cell contains genetic information, which, in essence, is a biological passport of an individual [5]. In our opinion, the donor (regardless of the type of donation - autologous or allogeneic) has the right to protect such information from unauthorized access and use in cases where such actions are not directly related to the production of BMCP. It is important to emphasize that donation is exclusively voluntary, no one can be forced to surrender biological material under any reason; the person has the right at any time to refuse the surrender procedure. At the same time, a certain confrontation with the right to privacy enters into the right to protect the health of the person to whom the BMCP will ultimately be applied (in the case of allogeneic donation). This explains the donor's obligation to provide information on past and existing diseases, information on the use of drugs, psychotropic substances, alcohol, as well as other data to ensure safe donation. Intentional non-fulfillment of the obligation, which resulted in harm to the life, health of the patient, medical employees, other persons, the donor bears the responsibility established by the legislation of the Russian Federation.

There is no doubt that the donor also has (3) the right to information, that is, he must be properly informed about the nature of the manipulation, its goals and consequences [6]. Compliance with this right is ensured by the mandatory presence of informed voluntary consent, the form of which was developed by the Russian Ministry of Health. By signing such a document, the donor agrees to the removal and subsequent use of biological material. At the same time, the medical organization is obliged to explain, among other things, information about the BMCP, for the production of which biological material is provided, the purpose of the BMCP, the manufacturer, the procedure for obtaining and using biological material, and possible consequences for the donor's health.

Despite the fact that a person's legal capacity ceases with death, the law provides for a series of rules aimed at (4) respecting the will of the deceased and a worthy attitude to his body. So, in the absence of a person's expressed will

in relation to the posthumous donation, biological material for the production of BMCP after his death is allowed upon written consent of one of his relatives, certified by the head of the medical department organization or notarized. In the absence of intravital consent to the posthumous donation and consent of the spouse or relative, donation is not allowed. In case of posthumous donation, biological material can be obtained from a corpse after stating death in accordance with Article 66 of the Federal Law of November 21, 2011 N 323 "On the Basics of Protecting Citizens' Health in the Russian Federation" with due respect for the deceased person's body and maximum preservation of its anatomical shape [7].

The rights that have ambiguous interpretation and controversial nature should be singled out as a separate group - this is the right to dispose of their biological material and the right to remuneration.

Due to the lack of indication in the legislation of the place of biological material in the system of civil rights objects, as well as obvious ethical problems, the free disposal of one's own biological material is supposed to be unacceptable. Although some authors express bold hypotheses that the ban on the sale of biological material does not exclude the possibility, for example, of donating it [8, p.244]. On the other hand, the donor can generally decide on the transfer or rejection of biological material, which can already be considered a form of disposal. But in the future, the medical organization "disposes" of the biological material: for example, unclaimed biological material is subject to destruction. In our opinion, the possibility of disposition should not go beyond the limits necessary for the production of BMCP, since this contradicts the norms of ethics and morality, as well as the ontological essence of man.

In close connection with the right to dispose of biological material, the donor's right to remuneration should also be considered. In many jurisdictions, there is a ban on the sale of biological material, which automatically makes a reward impossible, since it is impossible to qualify the transfer of biomaterial for money otherwise. At the same time, foreign studies of blood donation show that interest in blood donation increased in target groups when donors were offered remuneration [9]. Payment can not only attract potential donors, but also motivate them to donate blood on a regular basis [10, p.166]. But there is another point of view, which is that blood donation should be exclusively a matter of goodwill and based on the public consciousness of the need for such an action [11].

The key rule of biological material donation for BMCP is that it is absolutely free in all cases. There is some inconsistency with the legislation on blood donation and its components. As one of the principles of blood donation, the law singles out the principle of encouraging and supporting free blood donation and (or) its components. Encouragement and support are expressed in the fact that on the day of blood donation, the donor is provided with free food, and in case of blood donation during the year in the amount of two maximum permissible doses, the right to the priority purchase of preferential vouchers for spa treatment is granted. The Law on the BMCP does not contain either direct or reference norms on the encouragement or support of donors.

Conclusion

The development of cell products, their widespread production and effective use are objectively possible only if there is a basis - cell lines isolated from the biological material of the donor. It is important to develop legal standards that will reflect the balance of private and public interests, public requests for personalized treatment and the interests of an individual patient or donor. The collection of biological material - one of the first procedures in a long and difficult way for BMCP to enter the medical market, should be carried out in full accordance with the law. In turn, the system of normative legal acts regulating donation should be streamlined, which is currently not observed in Russia. "Russian law currently underestimates the importance of genetic information which can be extracted from human biological material and constitutes human biometric data" [12, p.40]. .

Findings

The development of donor rights protection mechanisms should be carried out in the following areas:

1. Formation of a licensing and control system for organizations that collect biological material in order to protect the donor's right to health.
2. Assignment of liability for coercion to donate, for the illegal seizure of biological material, for the use of genetic information contained in the cell, for the concealment of information on the consequences of donation and on the further use of biological material in order to protect the donor's right to privacy and the right to information.
3. Monitoring compliance with applicable law regarding posthumous donation.
4. The consolidation of the regime of circulation of biological material, taking into account belonging to a particular person.
5. Achieving uniformity in the system for encouraging blood donation and its components and biological material for BMCP.

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