



DOI: [https://doi.org/10.14505/jarle.v8.7\(29\).25](https://doi.org/10.14505/jarle.v8.7(29).25)

Problems of Legal Regulation of Human Organ and Tissue Transplantation Relations

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Suggested Citation:

Shevchuk, Svetlana Stepanovna *et al.* 2017. Problems of Legal Regulation of Human Organ and Tissue Transplantation Relations, *Journal of Advanced Research in Law and Economics*, Volume VIII, Winter, 7(29): 2241 – 2250 DOI: [10.14505/jarle.v8.7\(29\).25](https://doi.org/10.14505/jarle.v8.7(29).25). Available from: <http://journals.aserspublishing.eu/jarle/index>

Article's History:

Received September, 2017; Revised October, 2017; Published December, 2017.
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Abstract

This paper is devoted to research and analysis of the issues on legal regulation of the relations arising in connection with the removal of human organs or tissues with the purpose of their subsequent transplantation to a donor. The current national legal framework and lawenforcement practice in transplantation relations are investigated. The theoretical and practical problems affecting the provision and protection of the rights and interests of parties to these relations are analyzed. The necessity of further development and improvement of legal regulation of transplantation relations is substantiated. The scientific novelty of the work is that the authors, on the basis of studying the history of the formation and development of the institution of human organ and tissue transplantation, have made attempts to identify the main trends and directions of legislative support of this sphere of social relations and to substantiate the most constructive proposals in order to improve the corresponding mechanism of legal regulation.

Keywords: transplantation; transplantology; transplant; legal status of transplants; human organs and tissues; donor; recipient; removal of organs and tissues.

Jel Classification: K10; K19; K39.

Introduction

The issues of legal regulation of relations on transplantation of human organs and tissues have traditionally been paid close attention, since this method of medical intervention requires special treatment in the legal norms.

Transplantation is a special type of medical service in connection with putting a transplant from a donor to a recipient in order to save lives or restore health. However, it was this specific, actively developing method of medical influence on the human body that morals, deontology and law turned out to be especially unprepared to (Shevchuk 2001). The reason for this, in the authors' opinion, is, first of all, that transplantation of organs and tissues has its principal differences from conventional, traditional methods of treatment. Instead of the usual relations arising between the two parties – the provider of medical services and the patient, a more comprehensive complex relation emerges, the parties to which at the first stage are the donor and the provider of medical services, and subsequently - the provider of medical services and the recipient.

Another important feature of transplantation is that the success of this method of medical intervention depends, first of all, on the restoration of the functions of the transplanted organ or tissue - the transplant, and the less time has passed since the death of a donor and the removal of an organ (or removal of an organ from a living donor) and transplanting it to the recipient, the more is the hope for a successful outcome. That is why, from the biomedical point of view, the period of clinical death with artificial respiration and blood circulation (with the so-called 'brain death') is considered optimal for the removal of an organ for the purpose of its transplantation.

The issues related to the exercising by an individual or his/her close relatives or legal representatives of the right to agree or disagree, in case of death, to the removal of organs and/or tissues for transplantation, require more detailed rulemaking (both at the legislative level, and in subordinate regulations), while mechanisms for informing about the current legal regulation need some development and improvement. When using grafts removed from a living donor, there are not less specifics and moral problems: an individual acting as a donor does not need medical care, he/she actually is healthy, while as a result of medical interference his/her life and health are at serious risk, since it is obvious that the fact of removal even of a paired organ is anyway recognized as harming the health of the donor. The actual possibility of abusing the achievements in transplantology should not be underestimated, because the most valuable donor material has always been, and in the near future will be in deficiency; therefore, despite legislative prohibitions, it will be a source of extra-high incomes.

Impressive achievements of transplantology indicate positive trends in the application of this special method of medical intervention. The survival rates and overall life expectancy of recipients are improving, the timing of maintaining the viability of grafts after their removal from the donor's organism is increasing, the list of transplants is constantly growing, indicating the expanding prospects of using transplantation (Rapaport 1990).

The foregoing convincingly shows that the improvement of a special mechanism of legal regulation of relations on transplantation of organs and tissues is an essential and long overdue necessity. In addition, the lack of a sufficient legal framework undermines further progress in this field of medicine.

1. Methodology

In the course of work on this paper, such methods of legal science as historical, dialectical, logical and comparative legal were used. The historical method was used mainly in the study of the history of transplantology and transplantation legislation. The dialectical method provided an opportunity to study the legal mechanism for regulating transplantation relations in their development, connection and interaction with other institutions of law. The logical method was used, in particular, in the study and analysis of norms that represent the institution of transplantation. The comparative legal method allowed the authors to analyze and compare foreign legislation on transplantation of human organs and tissues.

2. Results

2.1. Legal Regulation of Relations when Grafts are Removed from Living Donors

Organs and tissues for transplantation may be removed from both a living donor (*ex vivo*) and from a corpse (*ex mortuo*), which entails significant differences in the legal status of the removal of transplants. Removal of a transplant for grafting before the biological death of the donor (that is, with a 'living heart'), in principle, contradicts the established for decades principles of resuscitation, which raises complex ethical and legal issues, the solution of which requires detailed development of a legal mechanism regulating the use of this special and unique method of treatment. The authors believe that the mechanism of legal regulation of relations on transplantation of organs and tissues should be based on the fundamental basics (principles) enshrined in the law, which ensure comprehensive accounting for and maximum protection of the rights and interests of parties to the emerging relations. These

principles include: the principle of optimal care for the interests of the donor, the principle of collegiality; the principle of respect for and observance of patients' rights; the principle of decommercialization of organ and tissue transplantation; the principle of integration into international organ transplantation organizations; the principle of inadmissibility of sale of organs and tissues, which should be reflected in the special legislation.

A special legislative act regulating the relations on transplantation of organs and tissues is the Act of the Russian Federation 'On Transplantation of Human Organs and (or) Tissues' (the Act on Transplantation), however, the adoption of this Act and the subsequent introduction of amendments thereto did not allow solving all legal and ethical problems arising during transplantation.

The lack of the content of the Act on Transplantation is visible. Firstly, transplantation as a method of medical intervention is proclaimed a means of saving lives and restoring health of people. The declarative nature of this provision is obvious, since no way of medical intervention can guarantee this. Secondly, the legislator has not made an attempt to prevent possible cases of abuse when using transplantation; therefore, the authors support the position expressed in legal literature that the above Act 'did not reflect the idea to prevent unlawful harm to the donor's and the recipient's health, pointing to the internal contradictions in the Act' (Krasnovskiy 1993).

Having enshrined in the law the possibility of removing organs and tissues from living donors, the legislator thus recognized as fair the restoration of health and saving the life of one person at the expense of causing harm to the health of another. Such a position is not accepted by all authors who believe that the 'radical way to restore justice in this situation, and at the same time, the best way to protect the interests of donors, is to prohibit *ex vivo* transplantation with criminal liability for violation of the ban', along with civil law responsibility (Krasnovskiy 1993). With this in mind, the authors believe that the debate on whether removal of organs from live individuals (*ex vivo*) is permissible is not over, despite the permission provided for by the law.

In science, the issue of the possibility of assigning transplantation to a medical experiment is actively debated. The authors tend to support a compromise position that takes into account the possibility of referring transplantation either to a method of treatment or to a medical experiment depending on the types of transplants, since the evolving branch of medical science – transplantology -which is obvious even now, will use as transplants more and more organs, the transplantation of which will certainly presuppose the initial carrying out of experimental studies.

The legal basis for the removal of organs and tissues is the contract of donorship. In the legal literature on the legal nature of this contract, various points of view were expressed. In accordance with one of them, an individual voluntarily, consciously, independently decides on the alienation of a biological substratum. He/she makes a deal to sell this specific product. Instead of the ceded organ, he/she receives monetary compensation – there is a relationship of purchase and sale. If there is a free transfer, then we are talking about an act of donating (Tikhomirov 1998). It seems such a position is erroneous. Despite the fact that the authors are inclined to relate grafts separated from the body to the category of things of a special kind, limited in turnover, they nevertheless believe that a graft cannot be considered as a subject of traditional sale and purchase or donation transactions. The contract on donorship of human organs and tissues is an independent type of the civil law contracts (*sui generis*).

To carry out transplantation of organs and tissues from a living donor, it is necessary to do: an objective medical justification for the operation, acknowledgment of medical suitability of the donor's organs and tissues and an acceptable ratio between the transplantation's significance for the recipient and the damage caused to the donor by removal of the graft. This ratio, as noted in the special literature, will be acceptable only subject that 'a treatment method that benefits the recipient does not harm the donor in equal or even larger proportions. For example, heart transplantation cannot satisfy this condition, owing to which it was possible to save life of the recipient, but at the cost of the donor's life' (Drgonec and Hollander 1991). In view of our recognized right to manage our lives, the authors believe that there is nothing illegal about the fact that with the consent of the donor, an organ that is vital and not subject to regeneration will be removed (a mother agrees to such removal, sacrificing her life to save the child's life). However, transplants from a living donor can be a paired organ, a part of an organ, tissue, the absence of which does not entail an irreversible health disorder.

Legal regulation of transplantation presupposes the formulation of medical and legal conditions (prerequisites) for removal for transplantation of organs and tissues from a living donor. The study of these conditions is of considerable theoretical and practical interest, taking into account the need to consolidate them in the law with a view to ensuring and protecting the parties involved in these relations. Medical conditions of removal of organs and tissues, in our opinion, should include: (1) the presence of medical indications of surgery in accordance with the general rules for performing surgical operations; (2) the presence of a genetic link between the living donor and the recipient, except for cases of bone marrow transplantation. This condition limits the range of possible donors to close relatives of the recipient and is caused by immunological problems. Reaction of rejection of a transplanted organ or

tissue as a result of biological incompatibility occurs according to the laws of immunity and is genetically determined; (3) comprehensive medical examination of the health of the donor: in principle, he/she should be practically healthy; (4) the absence in the donor of a disease that poses a danger to the life and health of the recipient; (5) the statement by a council of medical specialists on the possibility of removing organs or tissues from the donor for transplantation; (6) the removal of organs or tissues from a living donor is allowed only if no significant harm is caused to his/her health in accordance with the conclusion of a council of medical specialists. At the same time, the legislator does not determine what should be understood as 'significant harm'. In civil law, the concept of 'significant harm' is also absent. In criminal law, the medical severity of an injury caused to health is checked by an expert in accordance with the 'Rules of forensic medical examination of the severity of health harm', according to which a loss of an organ is a kind of intentional infliction of serious harm to health. There is a contradiction that removal of an organ from a living donor is permissible in case if no significant harm is caused to his/her health, whereas a loss of an organ is recognized as a serious harm to health. It is not possible to eliminate this significant contradiction within the framework of the Act on Transplantation. The contradiction is also found in the content of the norm of Section 2, Art. 1 of the Act on Transplantation, which establishes the permissibility of removal of organs and/or tissues from a living donor, and the norms of Art. 13 of the same Act limiting the possibility of removal from a live donor of a paired organ, a part of an organ or a tissue, the absence of which will entail an irreversible disorder of the health of the donor. It is not entirely clear how the concepts of 'significant harm to health' and 'irreversible harm to health' relate to each other. Discussing this condition for organ removal from a living donor, one more issue cannot be ignored: the conclusion of a medical council that no significant harm will be caused to the health of the donor is, without doubt, highly probable, probable, or possible, since all the circumstances (individual characteristics of the donor organism, his/her reaction to the removal of the organ, etc.) are quite difficult to account for. If the conclusion by a council turned out to be erroneous and as a result of the removal of the organ, significant harm is caused to the health of the donor, the question is put whether specialists who gave such a conclusion are reliable or not? The law does not give an answer to this question; (7) establishment of criteria for the recipient's suitability for organ or tissue transplantation, which should be understood as such a state that guarantees that, if the prognosis is good, the health and the life of the recipient will be preserved. It is not expedient to do transplantation if the patient's health condition is such that, even with a favorable prognosis of transplantation, it does not give hope for the preservation of life. It seems that the law should fix clear definitions of the criteria for suitability of recipients by their health as one of the conditions for transplantation.

The authors are inclined to designate the following as legal (judicial) conditions for removal of organs and tissues for the purpose of transplantation from a living donor: (1) conditions relating to the donor's personality: donors can only be over eighteen years old (except for bone marrow transplantation), fully capable. Consequently, under no circumstances can a minor or an incapable person act as a donor. By virtue of this rule, the consent of the parents or guardians to the removal and use of the organs or tissues of their child or ward for transplantation (except for the removal and use of bone marrow) has no legal effect (Moskop 1987, 110, 175, 179). In the legal literature, another position is expressed, according to which the donor, with whom a written contract is drawn up, must give his/her own permit, in case of his/her incapacity – his/her guardian should do so (except for a blood donor, where consent can be verbal) (Akopov 2000; Drgonec and Hollander 1995).

The authors consider it necessary to fix a rule in the law, according to which in the Russian Federation it is forbidden to remove organs or tissues from minors or persons who are not able to give a voluntary and intended consent. Such a ban will correspond to the provision of Part 3 of Article 17 of the Constitution of the Russian Federation that the exercise of the rights and freedoms of man and citizen should not violate the rights and freedoms of other persons. The state at the same time has the role of the creator and securer of guarantees and conditions for the exercising of human rights (Drozdova *et al.* 2016).

In exceptional cases, on the grounds and in accordance with the procedure established by the federal public health authority, it is allowed to remove the regenerated tissue from a person unable to give consent, provided that the following requirements are fulfilled: (a) there is no suitable donor who is able to give consent; (b) the recipient is the donor's brother or sister; (c) donorship can save the lives of recipients; (d) there is a consent to donorship received and processed in accordance with the law.

The authors intend to recognize the special significance of the donor's free informed consent to the removal of an organ or tissue, since it is based on the consistent development of the principle of individual freedom of the personality, which, in relation to medicine, is expressed in the freedom of a human to dispose of his/her life, health, body and its parts, including by giving consent to medical intervention and removal of organs or tissues.

2.2. Legal Regulation of Relations on Cadaveric Removal of Grafts

The legal regulation of relations on cadaveric removal of organs and tissues for the purpose of transplantation has its own essential specific features. Transplantation is allowed if it is justified by medical reasons, that is, there is a reliable probability of a successful outcome of an operation leading to an improvement or stabilization of the recipient's health, and there is no fundamental dissent between the persons defined by law for cadaveric removal of organs and tissues. With the spread of transplantation, the need for cadaver material increases, and the problem of paying for the removal, storage, delivery and transplantation of cadaveric organs and tissues (Sade 1999) is rightly raised in the literature.

Cadaveric removal of organs and tissues for transplantation may happen, if there is indisputable evidence of death recorded by a medical council. The removal of organs and tissues from a corpse is not allowed if the health organization at the time of removal was informed that during life this individual, his/her close relatives or a legal representative declared their disagreement with the post-mortal removal of organs or tissues for transplantation. An analysis of the content of this norm allows concluding that the legislator fixes the presumption of the consent by the individual, his/her relatives or legal representatives to the removal of organs or tissues after death. The wording of the norm in question needs to be adjusted, since it implies that the next of kin or legal representatives can declare their disagreement with the removal of organs and tissues during the life of the deceased person only, and while after death cannot say so, although it is obvious that the legislator had in mind the right of the said persons to declare their disagreement if there is no relevant will expressed by the deceased during his/her life.

The authors believe that the list of persons defined by the law, entitled to express consent or dissent to the cadaveric removal of organs or tissues of the deceased (spouse, children, parents, adoptive parents, adopted children, siblings, grandchildren, grandparents, other relatives, legal representatives of the deceased, and in the absence of the above persons – other persons who took upon themselves the obligation to do the funeral of the deceased) is unreasonably wide and considerably complicates the prompt solution of the question of the use of organs and tissues of the corpse for the purpose of transplantation, which, in turn, restricts the use of transplants to save lives and health, and creates artificial obstacles in further development of transplantation. It is impossible to decide which opinion should be given preference based on the content of existing rules of law. In addition, the unduly cumbersome nature of the norm under study is striking: there was no need to specify the list of close relatives, if, following that list, it is indicated that the right to give consent to the cadaveric removal of organs or tissues belongs to other relatives and other persons, practically unlimited.

In the literature, a point of view is expressed, according to which the position of the legislator about the presumption of an individual's consent to the cadaveric removal of organs or tissues is criticized (Maleina 1995; Akopov 2000). The authors uphold the view that, in the absence of a direct ban on the removal of organs and tissues after death, it is reasonable and fair to presume an individual's consent to the removal of organs. An organ removed from a corpse can save a person's life; therefore, when solving the problem under consideration, preference should be given to the interests of the needy recipient, and not to the alleged dissent to removal of organs by the deceased or other persons authorized by law. This is followed by the foreign practice (Roels 1990).

Doubt is also caused by the fact that an unlimited range of persons entitled to consent to the removal of organs, thereby actually acquires the authority to dispose of the body of the deceased and its organs, and in this case the body and organs of the deceased are assumed to be the objects of their rights.

The problem of using organs and tissues of a corpse in case it is unclaimed by relatives or other persons specified in the law remains unsolved. For such cases, the right to remove organs should be secured if there is no information about dissent expressed during life, based on the principle of presumption of such consent.

Transplantation of organs or tissues obtained from a corpse is allowed with the consent of the recipient expressed in writing. In this case, the recipient should be informed of possible complications in connection with the forthcoming surgical intervention, danger of the immune reaction of the organism, a real probability of the operation's success. The authors believe that the transplantation of cadaveric organs and tissues without the consent by the recipient, his/her parents or legal representatives can be made in exceptional cases, in particular, if a delay in the respective operation threatens the life of the recipient and it is at that moment impossible to obtain such consent.

In the literature, the problem related to parents' refusal to transplant cadaveric organs or tissues to their children based on religious beliefs is actively discussed. It seems to the authors that such a refusal cannot serve as a basis for rejecting this method of medical intervention, once this creates a danger to the child's life, while other less radical methods of treatment cannot save his/her life.

Another source of grafts is aborted fetuses. Use of aborted fetuses' tissues happens, in particular, in the case of transplantation of cells producing insulin, to diabetics, transplantation of brain cells to persons suffering from Parkinson's disease, thymus transplantation to patients with DiGeorge syndrome and many other cases. The wide spread of these diseases, the lack of transplants, as well as special properties of embryonic cells, expressed in their ability to take root in a foreign organism and regenerate, contribute to the increased interest in this source of biological material. The problem is that the use of aborted material is not provided with a legal basis, the legal status of fetal tissues is not defined, and according to departmental rules, the abortive material is to be disposed of. With the development of cell biology, experimental medicine has moved to a new level that dictated the need to form a regime for the legal regulation of the relevant relations, including with the goal of putting a barrier to any business and profit from the use of embryonic material.

2.3. Problems in Defining the Legal Status of Transplants

The legalization of the contract of organ and tissue donorship gave rise to a rather complex problem of defining the legal status of transplants as things of a special kind. In the conditions of the rapid development of medicine in general and transplantation of organs and tissues in particular, these objects of the material world are getting actively involved in the civil property turnover, in connection with which the legal science faces the task of developing the features of their legal status, including legal grounds, entailing the emergence of rights to these things. The unity of positions on the indicated problem among law scholars is not reached.

The solution of this problem is directly related, in our opinion, to the identification of attitude to the elements (organs and parts) of the organism, which ensure the natural biological process of its vital activity and are organically integrated with it. In their natural state, they cannot be regarded as something independent and possessing a sovereign status. 'It can hardly be assumed that an individual has the right to own his or her body and exercise the powers to possess, use and dispose of it as a thing. The physical shell of a person cannot be recognized as a separate independent object, because in itself it does not exist, but is an integral component of the individual' (Maleina 2003). However, when separated from the body, the organs and tissues of the human body become independent objects of the material world, possessing a set of properties capable of satisfying certain needs, in other words, they acquire the status of a thing if a thing in civil law means existent regardless of the subject spatially limited objects and phenomena of the material world both in their natural state, and adapted by humans to their needs. For civil law, of significance are only those things that have useful properties enabling to use them and to enter into their legal relationships in connection with them, i.e., things that can satisfy some human need.

The authors believe that the granting of organs and tissues separated from the human body by the status of things entails important legal consequences: they become a special kind of property rights of an individual from whose organism they are removed; obligatory relations arising from contracts of donorship (transplantation) having their object the actions by the obliged party to transfer the organs and tissues for transplantation are also related to them. Therefore, the position according to which the grafts are not unowned deserves close attention; on the contrary, their owner is the one from whose body they are separated (Magnusson 1992).

In case of recognition of the status of things for removed organs and tissues, the legal mechanism of responsibility for illegal manipulation with these things comes into play, and the donor has the opportunity to perform a variety of legal actions on disposing of his/her organs and tissues.

The involvement of organs and tissues of the human body into civil circulation becomes an objective reality, and it is impossible to ignore this fact. However, taking into account the peculiarities of their origin, removal, storage, use, as well as their significance and deficiency, the legal status of such things is characterized by significant peculiarities: they, according to Art. 1 of the Act 'On Transplantation of Organs and (or) Tissues of Humans', cannot be objects of sale and commercial transactions. However, such a prohibition is not kept by the legislator with due consistency. For example, the Federal Act 'On State Regulation of Foreign Trade Activities' provided that the Russian Federation's jurisdiction in the field of foreign trade activities is to determine the rules for the export and import of biologically active materials (donor blood, internal organs and other materials), and the order of their use, which indicates that the Act recognizes biologically active materials as the subject of purchase and sale deals, barter transactions. However, in accordance with Art. 15 of the Act on Transplantation, health care institutions, which are permitted to carry out operations in connection with removal and purveyance of organs and tissues, are prohibited to sell them.

Considering the essential features of the legal status of human tissues, they should, in our opinion, be referred to the category of things limited in civil circulation. This point of view is recognized and supported by many authors. Ennektserus once said: 'The body of a living person is neither a thing nor an object. To the human body

refers the fact that, from the circulation point of view, it is considered as a member or a part of the human personality (for example, hair on the head, gold tooth fillings). However, with the death of a person, the body (or the corpse) becomes a thing, although it is not, however, included in the property to be inherited into ownership. Similarly, separate parts and members of the body become things when they are separated from the living body. They are not ownerless; on the contrary, their owner is the person from whose body they were separated' (Ennektserus 1949). Trubetskoy expressed a view, according to which 'it is wrong that the corpse and members of the human body cannot be objects of rights' (Trubetskoy 2001).

Maleina also claims that the organs and tissues of a person are an object of the material world, related to the concept of things (Maleina 2003). Supporting this position, Belov points out that 'human corpses, parts separated from the human body, as well as discharge from the human body, properly isolated, are transformed into things whose belonging may very well be formalized with proprietary rights' (Belov 2004).

It is known that the peculiarity of the legal status of proprietary rights is that they can arise on the grounds expressly provided for by the law. In our case, the legal fact (ground) of the creation of a proprietary right to bodies and parts separated from the human body is a legal act - i.e., separation of an organ or a part from the body in the manner prescribed by law for the purposes of transplantation, as a result of which they acquire signs of discreteness, qualitative (target) assessment, ability to belong to parties, systemacity and legalization. The authors believe that the right of ownership to organs and parts of the body should be recognized in a living donor. The right of ownership to transplants removed from a corpse must be recognized by the medical organization that did such removal. The right of property to transplants, removed from a corpse, may not arise in the heirs of the deceased persons: they are not a part of the hereditary mass, since during the life of the testator he/she did not have the right of ownership to them. In the event if the organs and tissues of a person separated from the body are recognized as objects of the right of ownership and the donor becomes the holder of the right to dispose of them, it seems necessary to fix in the law the right of the donor for both free and compensated alienation of organs and parts of his/her body. Compensated alienation of organs and tissues means for us nothing more than fair remuneration to the donor for the damage caused to his/her organism resulting from the removal of an organ or a tissue, physical and moral suffering, as well as the risk of a very likely significant deterioration in health or even death. The donor should be given the right to decide to donate his organ or tissue free of charge or to demand monetary or other property compensation for the losses and sufferings. As is known, the issue of gratuitous and compensated blood and sperm donation is similarly solved, although this is a recoverable biological material, and no fundamental objections have been voiced to the commercial nature of such relations in the literature.

The authors see no reason why compensation should not follow a loss of personal non-property goods – health, personal physical integrity, physical or moral suffering. The right to compensation should arise irrespective of what motives the donor was guided by, giving consent to the withdrawal of an organ or a tissue. Talking about any enrichment of the donor, at least in view of the limited donorship abilities, is meaningless. Commercial nature can only be in a transaction for compensatory alienation of an organ or a tissue by an intermediary (non-owner).

The donor should be recognized as having the right to conclude a donorship contract and dispose of his/her organs and tissues both during life and in case of death. The contract of donorship on the cadaveric use of organs and tissues may also provide for compensation. A similar position is occupied by Maleina: 'I believe that an individual during his or her life can conclude an agreement on the use of his or her organs, tissues or ashes after death with advance payment or with the payment of part of the sum, the balance being paid to his or her legal heirs' (Maleina 2003). The authors propose to consolidate in Part three of the Civil Code of the Russian Federation such an independent kind of testamentary order as the disposal of organs and parts of the testator's body after his/her death.

An independent form of the donorship contract is the agreement on the delivery of donor material (transplants) to a bank of organs and tissues. In medical practice, cases of disposal of organs and tissues are widespread via contracts for storage and placement of organs and tissues in a bank (for example, it is widely practiced to place bone marrow in a bank, which is subsequently used for transplantation to patients suffering from leukemia).

Thus, the need for recognition of the proprietary right of ownership to transplants, which enables them to be disposed of, taking into account their special properties, is evident, in particular, by placing them in a bank or by giving consent to their use. After the death of a donor, transplants should be included in the hereditary mass.

The objects of transplantation (transplants) can be: heart, lung, kidney, liver, bone marrow and other organs and tissues, the list of which is set forth by the Ministry of Health of the Russian Federation in cooperation with the Russian Academy of Medical Sciences. Other organs and tissues that act as transplants include eyeball, cornea, skin, cartilage, cerebral hard shell, bone, pancreas, small intestine, and the list of organs and tissues used for

transplantation is constantly expanding. So, some publications were made about the first time successfully carried out operations on transplantation of a hand and a trachea.

The norms of Act on transplantation do not apply to organs, parts and tissues related to the human reproduction process, including reproductive tissues (ovum, semen, ovaries, testes or embryos), as well as blood and its components, although the literal interpretation of these provisions evidences that the transplantation of organs and tissues related to the process of reproduction is permitted by law, but is subject to judicial regulation in another legal source.

The Act on Transplantation provides for a different legal status for human organs and tissues, which makes it necessary to classify them. It seems that such a classification can be carried out by the following criteria:

- (1) depending on the physiological characteristics, organs are divided into: a) paired and unpaired. The meaning of this classification is expressed in the fact that only a paired organ can be removed from a live donor (for example, a kidney) for transplantation; b) regenerating and non-regenerating. An example of a regenerating organ is liver. A genetically related relative is taken a liver fragment to be transplanted to the recipient. In the donor, the cut organ is eventually self-healing, and the part transplanted, for example, to a child, grows to the natural size;
- (2) depending on the physiological functions, the organs are divided into reproduction process related (including reproductive tissues) and not related. The meaning of this classification is that organs and tissues of the second kind are subject to the legal regime status enshrined in the Act on Transplantation. Specific features of the legal status of organs and tissues of the first type shall be determined by special legislation, which, as noted earlier, is missing to date;
- (3) depending on the peculiarities of the procedure for removal and transplantation, organs and tissues obtained from a living donor and from a corpse differ.

Of important theoretical and practical interest is the classification of human organs and tissues, proposed by Maleina, who put as the basis for this classification the reasons for their rejection and the purpose of further use (Maleina 2003). The first group includes transplants (grafts), that is, organs and tissues removed for medical purposes for further transplantation. The second group includes organs and tissues alienated as a result of medical assistance, i.e., amputated body parts (limbs, tumors, teeth, aborted fetuses, and embryonic material). The third group consists of organs and tissues, the rejection of which is not associated with a disease or medical intervention (cut hair, expressed milk, skin removed after a lifting, etc.).

3. Discussion

Improvement of a special mechanism of legal regulation of relations on transplantation of organs and tissues represents an essential and long overdue necessity, and the lack of a sufficient legal base prevents further progress in this field of medicine. More detailed guidance is required in connection with the questions related to the implementation by an individual or his/her close relatives or legal representatives of the right to agree or disagree in the event of death for the removal of organs or tissues for transplantation. The solution of moral problems connected with the fact that an individual acting as a donor does not need medical assistance, and as a result of medical interference his/her life and health are seriously at risk is not permitted to be further delayed, since it is obvious, that the fact of removal even of a paired organ cannot be recognized otherwise but harming the donor's health. It is required to determine the features of the legal nature and content of the contract on the donorship of human organs and tissues, which is proposed to be considered as a self-contained version of a civil law contract (*sui generis*) with a special subject matter. It is necessary to legislatively prohibit the removal of organs or tissues from minors or persons who are not able to give voluntary and informed consent. It is substantiated that the list of persons determined by law for expressing consent or dissent on the removal of organs or tissues of deceased persons is unreasonably wide and considerably complicates the prompt decision on the use of organs and tissues for cadaveric transplantation, which in turn limits the opportunities to use transplants to save lives and health and creates artificial obstacles in the further development of transplantology.

Conclusions

In this article, an attempt is made to theoretically substantiate the need for further improvement and development of the institution of transplantation of human organs and tissues.

Proposals have been made to fix the fundamental grounds (principles) that ensure comprehensive accounting for and maximum protection of the rights and interests of parties to relations arising out of transplantation. Medical and legal conditions (prerequisites) for removal for transplantation of organs and tissues from a living donor have been developed. The study of these conditions is of considerable theoretical and practical interest, taking into

account the need to fix them in a law with a view to ensuring the protection of the parties involved in these relations. Proceeding from the fact that the need has arisen to determine the peculiarities of the legal status of transplants, it was rationalized that, when separated from the body, organs and tissues of the human body become independent objects of the material world, possessing a set of properties capable of satisfying particular needs; in other words, they acquire the status of a thing of a special kind. The recognition of the status of things in organs and tissues separated from the human body entails important legal consequences: they become a special kind of objects of the right of ownership of an individual from whose organism they are removed; obligatory relations arising from donorship contracts are associated with them.

It seems that at the stage of civil law reform it is necessary to once again discuss the content of the individual's rights to life, health, physical (mental) integrity, ability to dispose of these benefits when deciding on the removal of organs and tissues for transplantation purposes, and how to ensure proper legal protection of rights and interests of all parties to the relations arising from that.

The authors hope that the legislator will take into account their conclusions and proposals and will be grateful to everyone who will take part in the discussion of the issues raised in this paper.

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