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Some General Remarks and Legal Restrictions in Reproductive and Therapeutic Gene Modification in Russia

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ABSTRACT
The article is aimed at outlining approaches in the sphere of reproductive and therapeutic gene modification in Russia in terms of legal restrictions at the level of the studied legal prescriptions, considered also from the perspective of intellectual property. Other regulations in this sphere are considered along the way. The study is relevant as there is a number of normative prescriptions in this field that were not considered in earlier studies. Thus, the present study serves to fill in this gap. On the basis of analytical reflections on the information obtained from relevant sources and literature, the paper analyses normative prescriptions in Russia, which create patterns of biotechnological potential development and its use from the standpoint of legal restrictions in reproductive and therapeutic gene modification. The author consistently moves from the key points of one act to another in order to understand and outline approaches in this area adopted in Russia. The result of the study is the set of legal restrictions found in the current legislation. The important thing is the contribution to the improvement of the further concept of law-making policy, which should be aimed at the creation of systematic special legislation regulating the field of biotechnology and further improvement of restrictions, prohibitions and responsibilities that would not allow abuse in the form of transformation of human beings into the object of technical biomedical manipulations. The theoretical and practical significance of the results obtained is determined by the fact that foreign researchers will be provided with up-to-date scientific information on the state of Russian legislation in the field under study, which in practical terms will contribute to the understanding of the gap in the achievements of Russian and foreign researchers and practitioners in terms of their implications at the legislative level.

Keywords: health, reproduction, Russia, reproductive and therapeutic gene modification, legal restrictions, development strategy, laws, secondary legislation, intellectual property rights, patenting.

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INTRODUCTION

Biotechnology as a process, as mechanisms, as ways to manipulate living cells of plants or animals and humans to create different substances or technologies aimed at expanding knowledge in biology, medicine, engineering, etc., as a tool to diagnose human pathological conditions, as a means for their correction, as a human reproduction, the creation of new species of plants and / or animals, is developed by all countries of the world capable of this [1. P. 1-6; 2. P. 151-162]. Therefore, legislators need to focus on legally supporting activities connected with scientific research and the legal protection of the results of such activities. At the same time, today, the issue of conducting genetic research, including human genome and embryo editing, is not properly addressed in Russian legislation that contains neither explicit prohibitions nor permissions to edit a human embryo, thus being "obscure" and "ambiguous" [3. P. 46-56].

Thus, the aim of the study is to understand and outline approaches in the field of reproductive and therapeutic gene modification adopted in Russia from the point of view of legal restrictions at the level of the studied legal prescriptions, which are also considered from the perspective of intellectual property provisions.

As for the relevant approaches, the object of the study is considered in terms of legal restrictions established by the current Russian legislation in the area in question. By legal restrictions we understand the narrower subject area regulated by law, as, for example, the Federal Law dated 05.07.1996 № 86-FZ (in the edition of 03.07.2016) "On state regulation in the field of genetically engineered activity" included gene diagnostics and gene therapy, leaving behind other issues, etc.

The scientific novelty of the study is in the complex nature of the approach. Firstly, the range of national legal sources considered is wide, including the Integrated Program of Biotechnology Development in the Russian Federation up to 2020; the road map "Development of biotechnologies and genetic engineering" for 2018-2020; the Forecast of scientific and technological development of the Russian Federation up to 2030; federal laws: dated 05.07.1996 № 86-FZ (in the edition of 03.07.2016) "On state regulation in the field of genetic engineering", dated 03.12.2008 № 242-FZ "On state genomic registration in the Russian Federation", from June 23, 2016 № 180-FZ "On biomedical cellular products", etc.. Secondly, the aim of the study, namely to identify the restrictions imposed by the Russian legal order, is comprehensive. The absence of a significant part of the above-mentioned acts in the studies of the previous period (e.g., 10-15 years ago) makes it almost impossible to find any traces of their discussion.

The theoretical and practical significance of the results obtained is determined by the fact that foreign readers will be provided with up-to-date scientific information on the state of Russian legislation in the field under study, which in practical terms will contribute to the understanding of the gap in the achievements in this area of Russian and foreign researchers and practitioners in terms of their implications at the legislative level.

LITERATURE REVIEW

The present study was carried out on the basis of expert estimates found in the papers of both Russian and foreign researchers on the premise that the issue of reproductive and therapeutic editing of human genes and gene modification of plants and animals has been and is becoming an object of their attention. Among them are Janina Metje-Sprink, Thorben Sprink, Frank Hartung. (Genome-edited plants in the field) [1] and Jagdip Singh Sohal, Azhar Khan, Divyang Vats, Mukta Jain, Rathnagiri Polavarapu, G.K.Aseri, Deepansh Sharma (Chapter 6 - Applications of genome editing in pet world) [2], who consider general aspects of plant and animal gene editing; Tetsuya Ishii (Germline genome-editing research and its socioethical implications) [22] and Fernando Zegers-Hochschild, Juan Enrique Schwarze (Chapter 15 - The Chilean experience: Cultural and political factors shaping human embryo assessment during IVF) [32], who focus on the social and ethical implications of gene modifications, including in vitro-fertilized embryo; Cui-Cui Ma, Zhen-Ling Wang, Ting Xuab, Zhi-Yao Heab, Yu-Quan Weia (The approved gene therapy drugs worldwide: from 1998 to 2019) [10], who focus on the highly relevant fact that gene therapy is again used as a part of major treatment; David S. Younger (Health Care in the Russian Federation) [14], who touched upon the question of healthcare in Russia; the same issues are considered in the monograph "Law and modern technologies in medicine" [8] & others.

METHODOLOGY

Is based on materialist dialectics and implies the collecting of data through analysis of the legal acts and documents and descriptive approach to the legal regulations in the field under study likewise reflective practice.

The author in this paper proceeds from the objectively subjective assignment of any phenomena and processes of the external world and applied general scientific and special research methods, such as formal and dialectical logic combined with induction and deduction, hypothesis and analogy, analysis and synthesis, systemic analysis.

Thus, the method of systematic analysis and reflection on the ideas provided in the aforementioned articles, book chapters, etc., along with such operations as induction and deduction, is used in the course of consideration of the provisions of Russian legislation in the field under study and other acts and documents to clarify its key provisions and the relationship with other regulations; methods of formal and dialectical logic help to understand the relationship between science and technology and innovation; the materialistic view of the processes and phenomena of the external world as a whole makes the study proceed from the fact that gene engineering, human gene and embryo editing, while preserving the current paradigm of society and its objective achievements in the field of science and technology, it will inexorably change the consciousness of people towards the admissibility of this kind of intervention under the control of the state.

On the basis of analytical reflections on the information obtained from relevant sources and literature, the paper analyses normative prescriptions in Russia, which create patterns of biotechnological potential development and its use from the standpoint of legal restrictions in reproductive and therapeutic gene modification. The author consistently moves from the key points of one act to another in order to understand and outline approaches in this area adopted in Russia.

RESULTS

Obtained during the study and the undertaken analysis show and make clear that certain legal restrictions, identified in the course of the study (diagram 1).

Diagram 1: Legal restrictions identified in the course of the study

The analysis of the limitations presented has led to the conclusion that at present the formalistic model of the relationship between law and bioethics prevails in Russia with law playing a major role in regulating all kinds of biotechnological issues.

In this regard, the law-making policy in the area in question should be directed, in our opinion, towards the creation of systematic special legislation regulating the sector of biotechnology and further improvement of restrictions, prohibitions and responsibilities that would not allow abuse in the form of transforming of a human being into the object of technical biomedical manipulations. However, all these should not hinder scientific progress in order not to make a gap in ensuring the safety of the individual, his rights and freedoms in various areas. It is also about the risks of potential criminalization of the area that can be boosted by the absence of necessary regulation.

DISCUSSION

The major strategic document that determines the policy of the Russian Federation in the field of biotechnology is the Integrated Program of Biotechnology Development in the Russian Federation up to 2020 (hereinafter – Program) [4] that includes the road map "Development of biotechnologies and genetic engineering" for 2018-2020 (hereinafter – Plan) [5]. The following financing of the field of biotechnology is stipulated by the Program (Fig. 1).

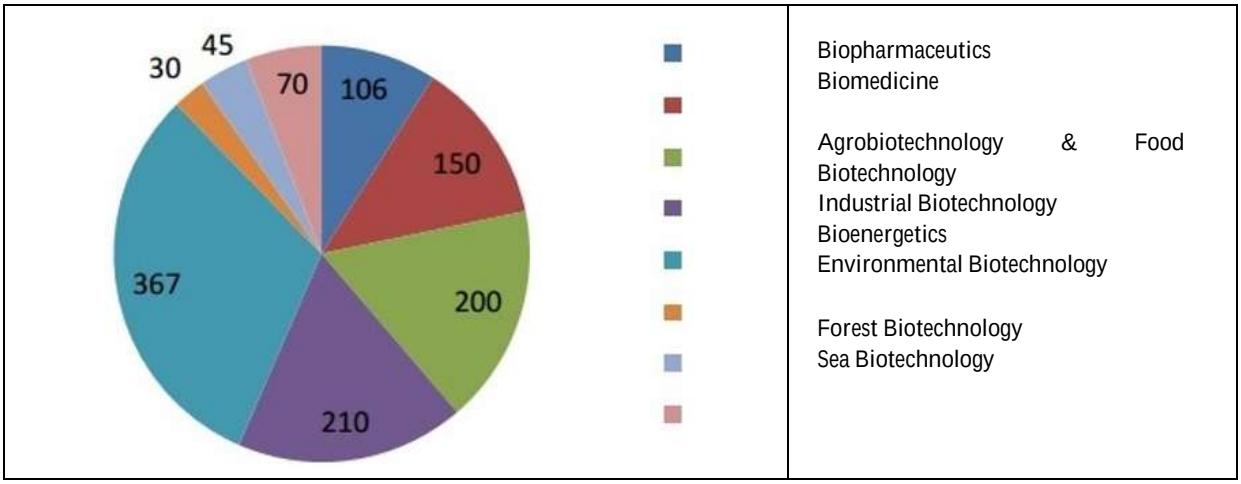

Figure 1: Funding allocation within Integrated Program of Biotechnology Development in the Russian Federation up to 2020 (billions of roubles). Sum total: 1,2 tn roubles

Taken from: The market report of biotechnology in Russia and the development sentiment, Frost & Sullivan. 2014. p. 12. https://www.rvc.ru/upload/iblock/e21/20141020_Russia_Biotechnology_Market_fin.pdf

In the Forecast of scientific and technological development of the Russian Federation up to 2030 [6] it is said that "Cellular, genomic, postgenomic technologies will serve as the basis for counteracting the spread of various types of human and animal diseases; obtaining biomaterials from renewable raw materials to replace traditional industries (chemical, food, pulp and paper, etc.) and the emergence of new products with unique properties; restoration of rare and endangered species of flora and fauna; conservation of biological resources of the oceans".

The "Strategy for the development of medical science in the Russian Federation for the period until 2025" (ratified by Order of the Government of the Russian Federation dated December 28, 2012 No. 258-p) [7] (hereinafter - the Strategy for the Development of Medical Science), for example, states that "the globalization of the economy, the development of science and technology, the scientific discoveries of the late 1990s and early 2000s in the study of the human genome contributed to the explosive growth of medical science." The legislative concept of "genome" in Russia is not stable today, while in many countries genomic technologies are regulated by special laws that actually determine the legal regime for their protection and use [8. p. 44-53].

At the same time, a number of other laws have been adopted and are in force in Russia:

- Federal Law dated 05.07.1996 No. 86-FZ (as amended on 03.07.2016) "On State Regulation in the Field of Genetic Engineering Activities" [9] (hereinafter - the 1996 Law) describes gene diagnostics and gene therapy, which are understood as a set of methods for detecting changes in the structure of the genome (genetic diagnosis) and a set of genetic engineering (biotechnological) and medical methods aimed at introducing changes in the genetic apparatus of human somatic cells in order to treat diseases (gene therapy - Article 2 of the 1996 Law). These methods are aimed of the both at treating the relevant diseases.

Yet "the procedure for carrying out genetic engineering activities and applying its methods to a person, tissues and cells in his body, with the exception of gene diagnostics and gene therapy (gene therapy)" is not subject to its regulation. The cited provision is fundamental both for ensuring both public health and well-being for future generations [10; 11. p. 85] and seems a tangible legal restriction established by the state in this specific area, where physicians and geneticists can make their efforts.

The following are the major tasks of state regulation of genetic engineering activities mentioned in this law:

- to establish the main areas of activity of federal bodies of state power, bodies of state power of the constituent entities of the Russian Federation, local governments, legal entities and citizens (individuals) in the field of genetic engineering;
- to establish the main provisions of the legal regulation of relations arising in the field of genetic engineering;
- to determine the mechanism ensuring the safety of citizens and the environment in the process of carrying out genetic engineering activities and the use of its results;
- to establish the legal framework for international cooperation of the Russian Federation in the field of genetic engineering;
- to create the conditions for the development of priority areas in the field of genetic engineering activity (Article 4 of the 1996 Law).

According to Article 5 of the 1996 Law genetic engineering is to repose on the following principles:

- safety of clinical researches on the methods of genetic diagnostics and gene therapy at the level of somatic cells;
- the general availability of information on the safety of genetic engineering activities;
- mandatory attestation of conformity of products containing the results of genetic engineering activities with the provision of full information about the methods of production and properties of the product;
- state registration of genetically modified organisms intended for release into the environment, as well as products obtained using or containing such

organisms, including these products imported into the Russian Federation [9; 11. p. 83].

- Federal Law dated 03.12.2008 No. 242-FZ "On State Genomic Registration in the Russian Federation" [12] (hereinafter - the 2008 Law) concerns identification of personality (Article 1 of the 2008 Law) by obtaining biological material, its accounting, storage, etc., processing genomic information by state bodies and institutions. Thus, it does not have a direct connection to medical and scientific activities. In our opinion, it establishes an algorithm of actions that does not contain legal restrictions, but only prescribes a certain model of behavior required by the state. On the other hand, registration itself is intended to delimitate the legally committed acts from the illegally committed acts;

- Federal Law dated November 21, 2011 No. 323-FZ (amended on December 27, 2019 and updates on January 13, 2020) "On the Basics of Protecting the Health of Citizens in the Russian Federation" [13] (hereinafter - the 2011 Law), being the main normative act in the field of human health [14. p. 1085–1102], specifies high-tech medical care, considering it as part of specialized medical care (according to Clause 1 of Article 34 of the 2011 Law), which includes "the use of new complex and (or) unique treatment methods, and also resource-intensive treatment methods with scientifically proven effectiveness, including cell technology, robotic technology, information technology and genetic engineering methods, developed on the basis of the achievements of medical science and related branches of science and technology" (as amended in 2015). Yet the procedure for making a list of types of high-tech medical care established by the authorized federal executive body includes, among other things, time limits that indicate the moment, when these types of high-tech medical care are included in the basic program of compulsory medical insurance (Clause 7.1 of Article 34 of the 2011 Law in 2016 edition). While the high-tech healthcare delivery is carried out using a unified state information system in the field of healthcare in the manner established by the authorized federal executive body (Clause 8 of Article 34 of the 2011 Law as amended in 2017). Thus, the 2011 Law does not prohibit the use of genetic engineering. Yet the Article 51 of this Law ("Family Rights in the Field of Health Protection") refers to the citizens' right for "medical-genetic and other consultations and examinations in medical organizations of the state healthcare system in order to prevent possible hereditary and congenital diseases in offspring" (Clause 1 of the Art. 51). While the Article 55 on the use of auxiliary reproductive technologies states that a man and a woman, both married and unmarried, have the right to the use assisted reproductive technologies (hereinafter referred to as ART) in the presence of mutual informed voluntary consent to medical intervention. A single woman also has the right to use ART, if she has given her consent to undergo medical intervention (Clause 3 of Article 55 of the 2011 Law). When using ART, one is not allowed to choose the sex of the unborn child, with the exception of cases, when the inheritance of diseases associated with sex is possible (Clause 4 of Article 55). Citizens have the right to cryopreservation and storage of their germ cells, tissues of the reproductive organs and embryos at their personal expense and other means provided for by the legislation of the Russian Federation (Clause 5 of Article 55 of the 2011 Law). Germ cells, tissues of the reproductive organs and human embryos cannot be used for industrial purposes (Clause 6, Article 55 of the 2011 Law). Citizens in the age between 18 and 35, physically and mentally healthy, who have undergone a medical and genetic examination (Clause 6, Article 55 of the 2011 Law) have the right to be donors of germ cells. When using donor germ cells and embryos, citizens have the right to receive information about the results of a medical and genetic examination of a donor, know his race and nationality, as well as other external data (Clause 7, Article 55 of the 2011 Law) [8. p. 202-206]. Thus, the Law provides for the possibility of medical and genetic examination in relation to ART and there are no norms regarding the genome or its research, which serves as an example of another legal limitation. Article 55 of the 2011 Law also refers to the procedure for using ART, established by the Order of the Ministry of Health of the Russian Federation dated August 30, 2012 No. 107n "On the Procedure for Using Assisted Reproductive Technologies, Contraindications and Restrictions on Their Use" (as amended on February 1, 2018) [15]. In accordance with the Order of the Government of the Russian Federation dated December 8, 2017 No. 1492 "On the Program of State Guarantees for the Free Provision of Medical Assistance to Citizens in 2018 and the Planning Period of 2019 and 2020" [16] IVF is listed as an assisted reproductive technology and high-tech medical care. Yet the current absence of the law on ART in Russia leaves a number of questions unanswered, namely the problem of legal status of embryos in the absence of consent for implantation by both spouses; the problem of obligatory storage of embryos by medical organizations and their right for their further use [8. p. 90-93; 17. p. 76-81].

- Federal Law dated June 23, 2016 No. 180-FZ "On Biomedical Cellular Products" [18] (hereinafter referred to as the 2016 Law) defines the specifics of limited civil circulation and the use of biomedical cell products that are complexes consisting of a cell line (cell lines) and excipients in substance or in combination with medicinal products for medical use and (or) medical products that have passed state registration (Clause 1, Article 2).

Moreover, according to Clause 1 of Article 1 of the 2016 Law, this law regulates relations arising in connection with the development, preclinical and clinical research, examination, state registration, production, quality control, implementation, application, storage, transportation, import into and export from the Russian Federation, destruction of biomedical cellular products intended for the prevention, diagnosis and treatment of diseases or conditions, the preservation of pregnancy and medical rehabilitation, and also regulates the relations arising in connection with donation of biological material for the production of biomedical cell products. Clause 2 of Article 8 describes the procedure for state registration of a biomedical cell product.

Clause 2 of Article 1 of the 2016 Law stipulates that this law does not apply to relations arising from the development

and production of medicines and medical devices, donation of human organs and tissues for transplantation, donation of blood and its components, using human germ cells in order to use ART, as well as on relationships arising from the circulation of human cells and tissues for scientific and educational purposes [19. p. 166–176; 20. p. 1125-1126]. That can be regarded as a number of legal restrictions from the perspective of the established regulation.

Clause 4 of Article 3 of the 2016 Law on the inadmissibility of creating a human embryo for the production of biomedical cellular products also presupposes embryos obtained as a result of IVF but not transferred to the uterine cavity of a woman, for example, remaining unused in this IVF protocol. Whereas Clause5 of Article 3 of the 2016 Law stipulates that the use of biomedical cellular products of biological material obtained by interrupting the development of a human embryo or fetus or disrupting such a process for development and production is prohibited. These two norms seem to be the "general" and the "special" ones, as Clause 4 establishes a general prohibition, while Clause 5 specifies it. In accordance with Clause 2 of Article 4 of the 2016 Law, only the cells of a person, whose death was pronounced, can be used for making a cell line. This is an instance of another general permission (or ban?).

Yet [11. p. 82], the question of the legal qualifications of such objects and their legal regime arises, as biomedical cell products obtained from the human body, like GMO plants and animals, are based on organisms created by nature, and therefore cannot be qualified as a product that is the result of only intellectual activity. It must be admitted that they are complex intellectual property objects, demanding a special legal regime. Thus, the fourth part of the Civil Code of the Russian Federation should be supplemented with new relevant provisions. These comments and opinions are based on the same views as the decision of the US Supreme Court in the case of the Association for Molecular Pathology et al. v. Myriad Genetic [569 U.S. 576 (2013)], which made it impossible to patent not only human DNA in natural form, but also isolated unmodified genes, since all of them, as products of nature, are not subject to patenting. However, the Supreme Court recognized synthetic DNA molecules that contain parts of the gene as patentable. On the other hand, [19. p. 166–176], considering their purpose and nature of their use, biomedical cell products are to count as medicines (they, as we know, are either patented or not, while the results of studies recognized as discovery cannot be patented, and new plant varieties and animal breeds created through the use of GMOs are recognized as protected results of intellectual activity and are registered in the manner prescribed by law as traditional breeding achievements). Their specifics have to be enshrined in law. It should be noted here that now, under the Article 1349 of the Civil Code of the Russian Federation [21] (hereinafter - RF CC), methods for cloning a person and his clone; methods for modifying the genetic integrity of human germ cells; the use of human embryos for industrial and commercial purposes cannot be objects of patent rights [22; 23. P. 799-812]. At the same time, *Rospatent* in Clause 2.2.2 of its Order dated December 27, 2018 No. 236 [24] excluded human cloning methods and products obtained by such methods from the objects of patenting, but allowed patenting of such methods and the products derived for human cells and tissues.

- Federal Law dated August 3, 2018 No. 280-FZ "On Organic Products and on Amending Certain Legislative Acts of the Russian Federation" [25] in Article 4 contains "a ban on the use of embryo transplantation, cloning and genetic engineering methods, genetically modified and transgenic organisms, as well as products made using genetically modified and transgenic organisms" as a part of the production of organic products (Clause 1, Article 4), which is another legal limitation in the field of genetic engineering, and gene modification.

At the same time, a number of provisions that indirectly relate to the practical problems of applying genomic technologies in healthcare can be found in the Decree of the President of the Russian Federation dated March 11, 2019 No. 97 "On the Basics of the State Policy of the Russian Federation in the field of ensuring chemical and biological safety for the period up to 2025 and further perspective" [26] (hereinafter - the Basics):

- "implementation of the genetic certification of the population, taking into account the legal framework for the protection of data on the personal human genome and the formation of the genetic profile of the population" (Subclause 7, Clause 13 of the Basics) (in fact, it does not create legal restrictions, asserting institutional regulation);
- "development of the production of domestic laboratory equipment to ensure microbiological (including molecular genetic) research" (Subclause 38, Clause 13 of the Basics) (in fact, it does not create legal restrictions, asserting institutional regulation);
- "improvement of regulatory framework in the field of transboundary movement of genetically modified organisms; joining the Cartagena Protocol on Biosafety, the Convention on Biological Diversity, the The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, as well as the The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety" (Subclause 9, Clause 14 of the Basics) (in the future, this provision may introduce legal restrictions in the form of prohibiting, for example, the import of certain GMOs).

Another document relevant to our study is the Order of the Ministry of Health "On approval of the Procedure of keeping the consolidated state register of genetically engineered and modified organisms, as well as the products obtained with the use of such organisms or containing such organisms, and the Procedure of putting the information into the composite state register of genetically engineered and modified organisms, as well as the products obtained with the use of such organisms or containing such organisms" dated July 5, 2016 № 476n [27], which speaks for itself. It should be noted that such practice exists, for example, in the EU (Regulation 1829/2003 [28; 29. p. 209-

218]). Acts like this, in our opinion, again are institutionally directed and cannot contain legal restrictions.

In practical terms, Russian scientists have been arguing for months about the right to intervene in the embryo gene [30; 8. p. 56-58; 73-78]. Denis Rebrikov, Russian molecular biologist, has previously stated that he plans to obtain permission to edit the embryo genome of a future child of a couple with hereditary deafness. In turn, Sergei Kutsev, the Ministry of Health's chief consultant geneticist and director of the Medico-Genetic Scientific Center, said he was preparing an appeal to the ministry to declare a moratorium on experiments to edit the embryo genome. In October 2019, the Ministry of Health reported that granting permission to edit the human genome in clinical practice is premature and even irresponsible, since at the current stage of development of genome editing technologies short and long-term possible complications have not been studied. This view is shared by the World Health Organization. The Genome Editing Center, which was opened in Russia in 2019, does not entail practical activity. "I personally believe that the technology of genome editing is not the most promising. It just seems impressive for both society and some experts", said Mr. Kutsev. In his opinion, a more promising direction is the ectopic gene expression [31].

CONCLUSIONS

The study showed that at present the approaches in the field of reproductive and therapeutic gene modification in Russia, captured in the analyzed normative prescriptions, do not allow to get unambiguous answers to a number of questions. For example, it is not clear whether the Clause 2 of the Article 4 of the 2016 Law, which states that only cells of a person, who is pronounced dead, can be used to prepare a cell line, establishes explicit prohibition or permission. And so on. Thus, further development and improvement based of scientific understanding and analysis of legal, moral and ethical components and mindful of both world and domestic experience in this field, is required [32. p. 127-133]. At the same time, it is necessary to work on improving the legal instruments allowing the physician, genetic scientists and common people to make a reasonable choice proceeding from "benefit-risk" criteria [33. p. 404-410] towards the technology of modification of human and embryo genes. Hence, further research and study of ethical and legal aspects of such application are required, rather than hiding from the solution of this problem and avoiding it.

As for the revealed legal restrictions in the area in question, they are present, on the one hand, as a result of progressive development of the field at the level of statutory approaches carried out by the state, and, on the other hand, they are the result of the Russian legal technique, which means that law application areas are formulated in reference. Thus, the 1996 Law focuses on genodiagnostics and genotherapy; the 2011 Law does not prohibit the use of genetic engineering methods developed on the basis of achievements of medical science and related branches of science and technology, including ART, but nothing is said about the genome or its research; the 2016 Law does not apply to the relations arising from the use of human germ cells for the purposes of ART and the circulation of human cells and tissues for scientific and educational purposes; the 2018 Law imposes a prohibition on the use of transplants. Provided that in practice the permit to edit the human genome in clinical practice is called premature and irresponsible, it seems that the current state of affairs is potentially capable of forming a backlog of the Russian Federation in this area.

At the same time, among the advantages of Russia's approach, in our opinion, is the desire to regulate the issues under consideration at the level of federal laws, and to a lesser extent at the level of subordinate legislation, which indicates that the state recognizes the importance of gene modification.

Yet, taking into account the danger of uncontrolled use of innovative genetically modified living organisms and biomedical cellular products, received from human organism, current stance of Russian legislators on creation of composite register of data on state registration of genetically modified organisms and also products, received with application of such organisms or containing such organisms, should be supported, and other issues of legal regulation of human genome modification should be brought to new level.

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