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TÍTULO: Medida de libertad en el contexto de la regulación legal de la investigación genómica: experiencia extranjera.

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RESUMEN. El artículo se basa en el uso de una metodología legal comparativa integral, y se analiza la medida de la libertad que prevalece en la práctica internacional en el campo de la regulación legal de la investigación genómica. El artículo incluye métodos de conocimiento tanto generales como especiales. La formulación de enfoques doctrinales sobre la evolución de los estándares para la regulación legal de la investigación genómica en los sistemas legales de identificación de diferentes grupos es imposible sin un análisis comparativo, realizado dentro del marco interdisciplinario, transfronterizos y cronológico. Los autores de este artículo enfatizan que la categoría "medida" es una de las claves en la formación de indicadores de análisis jurídico comparativo.

PALABRAS CLAVES: derecho, libertad, ruso, extranjero, investigación genómica.

TITLE: Measure of freedom in the context of legal regulation of genomic research: foreign experience.

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ABSTRACT. The article is based on the use of a comprehensive comparative legal methodology, and the measure of freedom that prevails in international practice in the field of legal regulation of genomic research is analyzed. The article includes both general and special knowledge methods. The formulation of doctrinal approaches on the evolution of standards for the legal regulation of genomic research in the legal systems of identification of different groups is impossible without a comparative analysis, carried out within the interdisciplinary, cross-border and chronological framework. The authors of this article emphasize that the category "measure" is one of the keys in the formation of indicators of comparative legal analysis.

KEY WORDS: law, freedom, Russian, foreign, genomic research.

INTRODUCTION.

On February 8, 2018, at the Council on Science and Education, President of the Russian Federation Vladimir Vladimirovich Putin, ordered to organize a large-scale genomic research in our country. “Domestic scientists have made significant progress in the relatively new interdisciplinary areas, such as life science, where research is being conducted at the interface of biology, chemistry, genetics, medicine, bioinformatics, and physics,” said the head of the state.

The genomic research was also intensified abroad. In this regard, one of the large-scale projects is the international project “Human Genome”. At the same time, when confronted with common and not yet known environmental challenges during the genomic research, Russia and other participants in the international humanitarian communication are interested in creating a balanced social policy in this area.

DEVELOPMENT.

One of the key concepts in forming the standards for the legal regulation of genomic research is the category of measure of freedom. Balancing between the "Scylla" of scientific progress and the "Charybdis" of centuries-old ethical maxims of human communication, the law-making institutions of different countries are on the path of gradual evolutionary changes in modern conditions. It is extremely important to understand such changes through the prism of a unified scientific criterion by which the authors chose a measure of freedom in law. This allows analyzing the problem with the greatest practical utility.

Methods.

The article includes both general and special methods of knowledge. The formulation of doctrinal approaches to the evolution of standards for the legal regulation of genomic research in the legal systems of different group identification is impossible without a comparative analysis, carried out within the framework of interdisciplinary (comparison of legal doctrine with related areas of knowledge, such as philosophy and ethics), interdisciplinary (comparative analysis of approaches used in comparative law, philosophy and theory of law, sectoral legal disciplines), cross-border (comparison of different national legal systems with each other and with the international law) and chronological (historical comparative analysis) approaches.

The authors of this article emphasize that the category "measure" is one of the key in the formation of indicators of comparative legal analysis. It is the measure that allows us relating the quantity and quality in the content, in our case the content of legal regulation.

Results and Discussion.***Measures of law and legal liberalism.***

Calling the paragraph of this paper as "measures of law and legal liberalism", we consciously emphasize that the idea of single construction of a measure of law is not developed at this stage in the jurisprudence development.

In many ways, the measure of law depends on the specific concept of understanding the law: natural law (jusnaturalism), positivism (in a regulatory or sociological way), materialistic legal thinking, and integrative concept [Voronin M.V. 2018]. Thus, when verifying the measure of law as applied to our problem, it is necessary to use the principle of methodological pluralism, which allows us considering the measure of law most completely and in different ways when carrying out the genomic research.

Realizing that the measure of law has not been found, or rather has not yet been formed by any of the well-known legal sciences in the implementation of genomic research, we have set the topic of this article - “measure of freedom in the context of legal regulation of genomic research...”.

It should be noted, that from our point of view, the following ways of verification (definition) of a measure of law are distinguished: establishment by the state (including various mechanisms for finding the key indicators of a measure), coordination of will (including contractual regulation), fixation of the revealed (open) objective regularity.

Let us name the key aspects influencing the legal regulation of genomic research: objectivity and urgency of the need for knowledge of the human genome, interdisciplinary nature of research, globalization.

Genomic research is an interdisciplinary problem, which is projected onto the interdisciplinarity of the issue of legal regulation of genomic research. Legal regulation is secondary in relation to the primary (directly economic, in our case concentrated on the object's cognition) relations.

The acute need for the implementation of genomic research is due to the advancement of science, the need to overcome certain diseases to solve other strategic tasks. All this generates a certain interest of the state and the society. But the conduct of genomic research is associated with the work of various research centers and institutes, individual scientists, often based and working in different countries and in different legal orders.

Under these conditions, it is important, but difficult to find a single measure of law and a measure of freedom when conducting genomic research. The measure of freedom in the research process is a problem associated with different social regulators - law, ethics, politics, religious norms. When exploring the map of the world, it is quite possible to assume that this problem can hardly qualify for legal mediation in some countries (for example, African).

It seems that the measure of freedom in conducting genomic research is associated with the freedom implementation at the level of specific legal relations arising under a single legal order.

From our point of view, genomic research should follow the construction of positive law-realization from the position of the national law and order, which means the national and public recognition of such studies, their sanctioning. Here, it is important to understand who has initiated such studies, what goals this subject has set for itself, how it seeks to express a social will and determine the social (and not only scientific) results.

These reflections lead us to the idea that legal liberalism becomes a certain facet of the embodiment of the measure of law. We can talk about legal liberalism when the category of freedom itself is thought of in a relative manner, and its restriction is connected with the establishment of both external and internal regulatory universes of personal behavior. The first, respectively, should include legal, religious and other types of social prescriptions; the second, in particular, - various options for the internal obligation of a person [Zakharova M.V., 2010, p. 953].

Depending on the presence or absence of individualization of the subject's will in determining the measure of freedom, one can speak of individual and collective liberalism. The collective form originates in the attitude of pre-state societies. Here, the idea of individual freedom is not and cannot be a priori. My freedom is only a material, a brick in the collective freedom of a community localized under the blood-related principle [Zakharova M.V. 2010, p. 953].

Legal liberalism of the individual type marked a fundamentally new stage in the development of mankind. It was a time when a person looked at “freedom” from the pre-experience positions, thereby creating theoretical prerequisites for actualizing the autonomy of his/her own will in the society [Zakharova M.V. 2010, p. 975].

If, with its collective analogue, liberalism has purely social bases and is ontologized exclusively within the framework of the constructions “individual - individual”, “individual - society”, then it acquires suprapositive and metaphysical meanings with its individualistic sound [Zakharova M.V. 2010, p. 962].

The construction of somatic human rights should be considered as one of the typical examples of the development of legal liberalism of the individual type.

This set of rights, as noted by Professor V.I. Kruss, is based on the fundamental ideological confidence in the person's "right" to independently dispose of his/her body: to carry out its “modernization”, “restoration” and even “fundamental reconstruction”, change the functional capabilities of the body and expand them with the technical-aggregate or medical means [Kruss V.I. 2000, p. 43].

Certain aspects of the legal regulation of genetic research are also included in the content of somatic human rights. What is the specific nature of this regulation and the measures of freedom of this regulation in the foreign legal practice?

Measure of freedom in foreign standards of legal regulation of genomic research.

The intensification of genomic research in the foreign scientific centers has also led to an increase in the number of studies assessing the problems of establishing a measure of freedom in conducting genetic research. Thus, the researches made by R. Frydman [La bioéthique, 2013], F. S. Collins [Collins F.S., 2010] determined the ethical standards for genetic research; S. Rich, S.S. Rich, B. Akolkar, P. Concannon, H. Erlich, J.E. Hilner, C. Julier, G. Morahan, J. Nerup, C. Nierras, F. Pociot, J.A. Todd [2009] entered into a discussion on genetic discrimination.

At the regulatory level, the measure of freedom of the researchers during genetic manipulations has also become the evaluation subject by the international law and national legislation.

The first case concerns the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997, approved by the UN General Assembly in 1998), the Council of Europe Convention on the Protection of Human Rights and Human Dignity With Regard to the Applications of Biology and Medicine, the Convention on Human Rights and Biomedicine (1996), the Recommended International Guidelines on the Ethical Issues of Medical Genetics and Genetic Services (WHO, 1997), the Helsinki Declaration of the World Medical Association "Ethical Principles of Medical Research on Human", the Recommendations of the Public and Professional Policy Committee of the European Society of Human Genetics for Mass Screening Programs, Data Storage and DNA Banks for Medical Research, and Provision of a Genetic Service, the International Declaration on Human Genetic Data (UNESCO International Bioethics Committee, 2003), the Protocol to the Council of Europe Convention on Biomedicine and Human Rights, the Draft Recommendations "On the Ethical and Legal Protection and Safety of Genetic Medical Research in the CIS Member-States" (Permanent Commission of the CIS Interparliamentary Assembly on Science and Education, 2006). The main purpose of these documents is to develop common approaches that allow, on the one hand, protecting human rights, and on the other hand, making the most effective use of the achievements of modern science in healthcare.

In the second case, two major problems are subject to substantive evaluation: genetic testing and genetic therapy.

Genetic testing, in particular, is provided for in the French Law No. 2011-814 regarding bioethics [Speranta Dumitru Liberté de procréation et manipulation génétique. Pour une critique d'Habermas Raisons politiques, 2003]. Israeli practice on the issue of genetic testing looks quite imperative in a number of cases; for example, in the case of the procedure for obtaining Israeli citizenship, when there is no other evidence of Jewish blood from a potential applicant, as well as when planning maternity and paternity in the presence of a child in the family with congenital anomalies,

chromosomal (Down syndrome) and other hereditary diseases, before performing IVF, if according to the obstetric history, the mother has at least two spontaneous miscarriages in the early pregnancy stages [Guy Rosner, Serena Rosner, 2009].

Thus, Israel, due primarily to domestic political support for the genetic identity of the Israeli nation, demonstrates, in our opinion, clear elements of restricting individual freedom. In the states with multinational identity (such as Russia, the USA, Singapore, Canada, etc.), this practice would have been impossible a priori.

Genetic therapy, in this case, as experts note: “The main difficulties around genetic therapy are associated with the definition of the medical technology itself, which does not fall under the general mode of medical intervention regulation. The medical worker performing the manipulations operates in the experiment mode. He/she cannot definitively predict the effects of treatment with the biomedical cell products. Additional difficulties arise when applying genetic therapy to the unborn” [Romanovsky G.B. 2017, P. 265]. In this regard, it has appeared the claims of disabled children against the doctors and parents who have refused to give recommendations on the artificial pregnancy interruption in the foreign judicial practice. Even the term “unlawful survival” has been developed [Hintz J., 2006].

In the countries of the European Union, the all-European integration practice is also an additional (regional) level of protection of individual rights in the genomic era and the establishment of the degree of freedom of the actors when conducting genetic research.

We should also note the Directive 2001/18/EC dated March 12, 2001 “On the Deliberate Release of Genetically Modified Organisms into the Environment”. The authors of this directive, guided by the determinants of protecting human health and environment, offer the participating countries a so-called permissive mechanism for the release of genetically modified organisms into the environment. The directive stresses that:

- Living organisms, released in any quantities into the environment for experimental purposes or as a commodity product, may multiply and spread beyond the state's borders, thus affecting other EU Member States. The effects of such emissions on the environment may be irreversible;

- It is particularly important to observe the moral principles recognized by the Member States, when deliberately releasing or placing on the market the products containing GMOs or the products manufactured from GMOs, the EU Member States may consider moral aspects.

The measure of freedom when working with GMOs in the common European space is directly dependent on ethical maxims.

It is interesting to note that according to this directive, when defining the term “genetically modified organism”, a human should not be considered as an organism. However, the examples of creating chimeras have already been made public in the scientific practice. Back in the year 2011, the press of Great Britain spreaded the information that the laboratories of three educational institutions made the experiments on crossing the human and animal embryos.

It should also be noted that with rare exceptions, such a global problem as the protection of human rights in the genomic era has not been brought to the constitutional and legal level. Switzerland is one of the exceptions in this regard. The state, which is one of the last among European countries, has given active suffrage to women in the matters of determining the constitutional and legal status of an individual in the genomic era, occupies a progressive and extremely innovative position - Articles 119 and 120 of the Constitution [Thomas Fleiner, Alexander Misic, Nicole Töpperwien, 2005].

In general, when conducting genomic research, we can observe a situation where the natural scientific knowledge is far ahead of its legal reflection in this area. As a consequence, there is the initial and subsequent gap in this sector of legal regulation.

The universalization of establishing the measure of freedom in this field also did not take place, which might be explained by the diversity of national views on law as such; for example, there was

no such imperative approach to genetic testing in the Russian Federation, which was observed in Israel.

The frameworks of genetic testing in our country is defined in Article 15 of the Family Code of the Russian Federation, which provides for the possibility (but not the need!) of medical examination of persons entering into marriage, as well as in the Order of the Ministry of Health of Russia No. 457 dated December 28, 2000 "On Improving Prenatal Diagnosis in the Prevention of Hereditary and Congenital Diseases in Children". This document establishes: "If there are some indications, recommendations should be given regarding abortion".

In summary, a comparative legal analysis of various approaches in the legal regulation of genomic research showed that there is a clear gap between the initial and subsequent order in the field presented in the international legal practice. At the same time, the measure of freedom in this matter largely depends on the legal traditions established in various national legal orders and cannot be standardized in a universal manner.

CONCLUSIONS.

Humanity has entered an era when the Latin maxim of "Terpora mutantur et nos mutamur in illis" ("Times change and we change with them") is becoming more and more acute. At the same time, the scientists act in two ways: both as active actors of scientific activity and (partly) objects of social reconstruction in a particular subject area.

To some extent, discovering not only the world not previously known, but also Pandora's box, genetic scientists from different continents and countries should understand that the absolutization of "individual" human freedom in the society always carries a threat to the existence of mankind as a whole.

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