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CONCEPTUAL ISSUES RELATED TO LEGAL SELF-REGULATION IN THE FIELD OF GENOMIC RESEARCH IN RUSSIA

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Abstract: Currently, the human genome is actively studied and these study results are often regarded by society as revolutionary. However, scientists involved in such research make different forecasts regarding its future achievements and practical application. This significantly complicates the process of setting certain limits to relations that should be legally regulated and protected. These arguments are justified by the legal support of the relevant relations in some countries. The article analyzes the basic guidelines developed by professional genetic associations at the international level and draws several significant conclusions that define the conceptual foundations of the self-regulation of genomic research in the Russian Federation. The study aims at considering the Russian legal mechanism of self-regulation in the field of genomic research. Its methodological basis is the theory of knowledge and the universal method of materialist dialectic. The authors of the article also use such general scientific methods as formal-logical and systematic methods,

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description, observation, comparison, analysis and synthesis. They have concluded that it is necessary to enshrine several provisions and professional requirements for self-regulatory communities: compliance with ethical standards in scientific research; informing (both the population and medical community) through the implementation of educational programs; correlation of genomic studies with good clinical practice and evidence-based medicine; consideration of the study results of the human genome as personal data; differentiation of medical and non-medical activities in the field of genome.

Keywords: legal regulation, self-regulation, genome, genetic counselling, limits of informing patients, human rights.

1. Introduction

Since genomic studies are gaining popularity in Russia and abroad, it is especially relevant to legally regulate this activity both in the field of scientific research and in the provision of medical services to the population.

While considering the legal regulation of genomic studies, we can proceed from the three-component approach, including state regulation, self-regulatory organizations and individual rights. Their interaction does not give any of them priority but is mutually complementary.

The study aims at considering the Russian legal mechanism of self-regulation in the field of genomic research. This article addresses issues of self-regulation in the field of genomic research. The legal mechanism of self-regulation solves the following issues:

1) To receive informed consent to conduct genetic studies and protect the confidentiality of information obtained by its results;

2) To involve self-regulatory associations of medical geneticists into the development of national standards for the quality of medical services in the field of genetic studies and requirements for medical organizations and medical workers providing them;

3) To validate the legal status of a person providing consulting services in the field of genetic studies and other areas related to the definition of a treatment strategy for genetic diseases

and the use of assisted reproductive technologies (genetic counselors).

2. Literature Review

Many scholars and experts analyzed the legal mechanism of self-regulation in the field of genomic studies from the conceptual perspective. For example, A.M. Gerasimov considered the moral limits of genomic studies and biotechnologies as the basis for forming the legal space of innovative medicine. A.R. Sakhipgareeva emphasized the need for state control in the interpretation of genomic studies and medical applications in the United States of America. E.V. Alimov conducted a comparative analysis of the legal regulation of genomic studies in Russia and the USA. J.P. Evans and M.S. Watson (2015) examined genetic testing and FDA regulation and concluded that overregulation hinders the formation of genomic medicine. K.P. Rippe and A. Willemsen proposed the idea of precaution, i.e. ethical requirements for the regulation of new biotechnologies in the field of environmental protection. In addition, many other scholars addressed the issues of self-regulation mechanism in the field of genomic research.

3. Methods

The methodological basis of this study was laid by the theory of knowledge and its universal method of materialist dialectic. We also used such general scientific methods as formal-logical and systematic methods of scientific cognition, description, observation, comparison, analysis and synthesis.

The main conclusions and suggestions in this study were based on the analysis of theoretical sources and regulatory documents, comparison, generalization and modeling.

To analyze private medical practice, we used the dialectical method of studying social and legal phenomena. In addition, we utilized the logical method (when delivering the material, drawing recommendations, suggestions and conclusions), the method of systemic analysis, the method of comparative law, the historical method, modeling, the method of addressing the conclusions of institutional economic theory, taxation and other sciences.

While considering the mechanism of self-regulation in the field of genomic studies, we also used the

general method of cognitive analysis and special scientific methods, including system-structural, technical-legal, case study, comparative law, etc. Their application allowed us to analyze the subject under consideration in the interdependence of its components, their integrity, comprehensiveness and objectivity.

4. Results

While considering issues of self-regulation in the field of genetic and genomic studies, we should pay attention to the different formation of medical professional communities in Europe and Russia. In the late 19th century, the European health care system headed in the direction of forming medical communities. They accepted the responsibilities of both regulating medical activities by establishing ethical and professional requirements for their members and performing public health functions, i.e. developing hygienic requirements for food products, sanitary conditions for urban settlements, etc. Subsequently, many countries that have retained a large number of private medical practice or countries with a developed system of family doctors and general practitioners, make these communities responsible for assessing professional skills, including developing professional standards, certifying specialists and providing them with work permission (Gerasimov, A.M., 2019). At the same time, many medical associations in Western countries have retained an element of secrecy, which in some cases resulted in the predominance of corporate interests over public ones (Pellegrino, E.D., Relman, A.S., 1999).

In Russia, the development of health care as a system of public services is traditionally associated with social reforms of the 1860s and the formation of zemstvos (county councils). In some provinces, they monitored public health; therefore the medical system formed during this period was called "zemstvo medicine". By the end of the 1870s, zemstvos were introduced in 34 provinces of European Russia, Bessarabia and the Province of the Don Cossack Host.

Thus, regulatory functions were assigned to the Russian local self-government. At the same time, Russia formed public communities of doctors, i.e. voluntary non-governmental associations of medical workers of all specialties. Despite the extensive

development of medical communities in Russia, their activity was directed towards self-organization and public health issues rather than issues of self-regulation (Sakhipgareeva, A.R., 2018). The predominance of self-organization over self-regulation has partially survived to this day.

While analyzing self-regulation in Russia, we mostly considered it as an alternative to state regulation and, accordingly, as an instrument for moving from relatively heavy-handed regulation to its milder forms (Kirillova, E.A., Pavlyuk, A.V, Mikheyev, A.A., 2019).

In the rest of the world, self-regulation evolved differently. There are almost no foreign laws on self-regulation or self-regulatory organizations. In foreign countries, self-regulation was formed historically and developed evolutionally. On the contrary, it was imposed in Russia, which is the fundamental difference. The state should not intervene in voluntary self-regulation. The overall logic is as follows: self-regulatory organizations operate in a general regulatory framework without any special additional restrictions or requirements for voluntary self-regulation. If a group of organizations in the field of genomic studies wants to unite and improve quality standards, this should be welcomed.

Self-regulation is understood as an independent and initiative activity carried out by professional subjects. It aims at the developing and establishing standards and rules of such an activity, as well as monitoring their compliance. This law introduces requirements for all self-regulatory organizations and special procedures for their registration. Such requirements are as follows: representative membership, specialized structure, standards and rules of professional activity, additional property liability of each member to consumers of their services and information disclosure.

A separate issue of developing self-regulation in Russia is to define the subject of self-regulation associated with the organization of the corresponding scientific and medical community and the conduct of scientific and applied studies in the field under consideration (Kurakova, N., 2008). The main amount of funding in this sphere is provided by neither the Ministry of Health nor the medical community itself. There is a professional standard for providing genetic counseling. Among other

professional requirements, it requires only the knowledge of "laboratory molecular-genetic methods", which might imply gene diagnostics.

The development of self-regulation in the field of genomic studies will create an institute of systemic opposition to the state regulator and provide a mechanism of property responsibility for the results of such activities. In the future, a qualified professional community might be entrusted with some powers in the sphere of industry-specific regulation. It is universally accepted that self-regulation demonstrates greater flexibility and adaptability if compared to state regulation. The costs of monitoring the implementation of established standards and rules significantly reduce and the effectiveness of control increases. In several cases, professional communities perform these functions more efficiently than officials do. This is confirmed by both the Russian practice in the related spheres and international experience. The adoption of the law "On Self-Regulating Organizations" gave an incentive to the development of self-regulation and caused a broad public discussion. At the same time, there is a strong need to adopt a whole range of regulatory legal acts, amend the corresponding industry-specific legislation and explain advantages of self-regulation (Mashkova, K.V., Varlen, M.V., 2019).

Nowadays the Ministry of Health of the Russian Federation, the Ministry of Science and Higher Education of the Russian Federation and the Ministry of Labor and Social Protection of the Russian Federation are not ready to transfer some powers to regulate this activity into the hands of professional genetic associations. However, the inevitable modernization of the health care system, standardization of labor and conditions for conducting scientific research cannot do without self-regulatory organizations since they will become an integral element of a tri-partite partnership. Thus, it is necessary to undertake concrete steps to develop "voluntary" self-regulation in the field of genomic studies. Once such organizations have proved themselves and developed their own law enforcement practice, several state functions can be delegated to them. The main goal of administrative reforming in Russia is to overcome the total regulation of all economic activities, reduce state interference in economic affairs and put

an end to excessive state regulation (deregulation). One of the mechanisms ensuring a smooth transition is the ability to use self-regulation. This mechanism is represented by a scheme when subjects of legal relations in the field of genomic studies independently establish rules for their functioning in the above-mentioned industry. Importantly, they independently monitor the implementation of these rules because it is not enough to simply establish certain rules, they must be strictly enforced by imposing sanctions on violators (Commission de l'éthique en science et en technologie, 2019). Among other things, this change involves the existence of specific guarantors ensuring the implementation of such rules, i.e. self-regulatory organizations of the professional genetic community. If this process has a regulatory impact, independent regulation is more preferable than state regulation from the viewpoint of public welfare.

The improvement of self-regulation principles in the field of genomic studies will help the Russian and foreign organizations reach a common ground.

4. Discussion

The preliminary analysis of foreign and international self-regulation in the field of genetic studies and related spheres indicates a general tendency to independently develop, approve and fulfill industry-specific standards by professional geneticists, as well as to exercise self-control through permitting and prohibiting medical practice (Richards, S., Aziz, N., 2015).

The self-regulation of genomic studies, reproductive technologies and genetic engineering activities is conducted by the UK, Germany, the Netherlands, France, Japan, Switzerland and Austria. While considering the best practice of foreign countries in this sphere, we revealed the following mechanisms of self-regulation: a special system for regulating genomic studies and the use of their results, the form of organization of professional genetic communities, information on sources of funding.

However, the presence of self-regulatory genetic organizations in foreign countries does not mean that state authorities have disengaged themselves from the traditional regulation of this sphere of public relations (Evans, J.P., Watson, M.S.,

2015). The above-mentioned countries have enough laws and regulatory acts governing the process of genomic studies but these documents establish certain limits (boundaries) that geneticists cannot go beyond (Rippe, K.P., Willemsen, A., 2018). Within the boundaries established by states, professional self-regulatory communities are provided with all the powers to establish, implement professional and ethical standards and control their compliance (O'Reilly, M., Jambou, R., 2015).

The effective decoding of the human genome makes it necessary to develop national and international legislation in the field of genomic studies and genetic engineering. Modern medicine gets new opportunities for treating congenital defects and combating cancer. However, possible interference in the human genome and its unpredictable consequences require (*or have already required*) to reconsider the ethical principles of research activities in biology and medicine.

Since the world community is concerned with possible adverse consequences of the work on decoding the human genome, it has adopted several framework declarations protecting human rights in this area.

For example, the Universal Declaration on the Human Genome and Human Rights was issued by the United Nations Educational, Scientific and Cultural Organization on November 11, 1997.

The International Declaration on Human Genetic Data was adopted unanimously and by acclamation at UNESCO's 32nd General Conference on October 16, 2003.

The United Nations Declaration on Human Cloning was adopted by General Assembly resolution 59/280 of March 8, 2005.

The General Conference of UNESCO adopted by acclamation the Universal Declaration on Bioethics and Human Rights following the report by Commission III at the 18th plenary meeting on October 19, 2005. There is also the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and the Convention on Human Rights and Biomedicine of the European Treaty Series No. 164 adopted by the Council of Europe (Oviedo, April 4, 1997).

It is crucial to ensure the legal development of the following aspects related to genomic studies:

1. Protecting individual rights and personal data;
2. Ensuring the general safety of genetic engineering activities;
3. Recognizing the legal use of certain methods;
4. Determining requirements for reagents, material and equipment used in this area;
5. Securing the national genome.

These issues cannot be resolved without the broad involvement of scientific and medical communities.

In general, the results of genetic studies can be used for the following areas:

1) Identifying genetic predispositions and assessing risks of their development;
2) Projecting future treatment and preventive measures;
3) Planning a family with the use of assisted reproductive technologies;
4) Conducting comprehensive risk assessment for voluntary personal insurance;
5) Assessing risks associated with employment;
6) Ensuring the further scientific research.

Genomic studies are currently evolving in Russia and go beyond the framework of medical and genetic counseling that has previously developed. Genetic counseling is provided by a genetic scientist and is expressed by the communication between the patient/patient representative/spouse and the doctor on the congenital defects that run in the family. Preventive medical and genetic counseling is also helpful for spouses planning a pregnancy or as part of preventive examination for their liability to diseases. Such uncontrolled counseling is primarily based on identifying pathologies of the Mendelian character and collecting family analysis, while techniques of molecular biology are secondary (Comité consultatif national d'éthique pour les sciences de la vie et de la santè, 2018). Genomic services are based on decoding the genome (clinical exome) which is the starting point for the analysis of genetic data. Commercial organizations conducting genomic research offer a wide range of services, including the carriage of genetic diseases and liability to diseases, potential reactions to certain drugs, recommendations on nutrition and fitness (metabolic profiles and food intolerance, the impact of physical exertion), personality traits, origins and

belonging to nationalities and haplogroups (Rippe, K.P., Willemsen, A., 2019).

Medical and genetic counseling is legally regulated as the field of medical activity (a draft professional standard for a geneticist has been developed) and self-regulated by the Russian Society of Medical Geneticists and the Committee on Biomedical Ethics at the Medicogenetic Research Center named after N.P. Bochkov. Medicogenetic counseling implies informed voluntary consent to the processing of personal data, including the possibility of transferring such data into the regional segment of the Federal Register of Persons suffering from life-threatening and chronic progressive rare (orphan) diseases, the collection of biomaterial and its transfer to another medical, scientific-research institution to conduct studies while maintaining the confidentiality of personal data. This difference between medicogenetic and genomic counseling is typical not only of Russia but also of other countries, in particular the USA (however, a specialist in medicogenetic counseling is not a doctor in this country) (Alimov, E.V., 2019).

Molecular genetic testing based on partial or full genome sequencing raises the question of limited informing (of patients) at the legislative level. In most cases, the amount of information received goes beyond the scope of the initial task (Romanovskaya, O.V., 2013). It refers to additional results, such as determining potentially significant changes in the human genome that were not the reason for conducting the study, changing approaches to evaluating the study results, obtaining additional information due to the development and improvement of molecular genetic technologies and establishing family ties and incorrect ethnic identification.

When random or additional results are obtained, re-informing can be undesirable as it violates the patient's right to not know or even cause psychological trauma. Since there is no legal obligation to inform patients about additional study results, it is necessary to develop professional and ethical standards at the level of self-regulatory genetic organizations that recommend providing such information in specific cases where the potential benefit to the patient is significant and the burden on the geneticist is not too noticeable. Specialists in this sphere need to respect

the private life of a person and their right to not know the results of genetic testing along with the patient's right to receive objective information about their health (Laviolle, B., Perche, O., 2019). However, a balance between one's free will and objective informing is achieved through preliminary consulting on issues relating not only to the risks and consequences of genetic testing but also to the possibilities of re-evaluating its results and their subsequent use in the field of general health care. The professional and ethical requirements under development should include a list of genetic abnormalities and defects related to random and additional results that must be reported regardless of the patient's will. The specific guidelines adopted by self-regulatory genetic organizations should also determine the sequence of actions and roles of all the parties involved (specialists and patients) in the process of disclosing information about the study results.

There is a need to re-inform the patient if approaches to assessing the study results have changed or additional clinically relevant information has been obtained due to the development and improvement of molecular genetic technologies.

In this regard, we need to distinguish between the legal consequences of genetic studies aimed at obtaining general information and choosing a particular treatment strategy with due regard to the risks of developing some genetic diseases.

5. Conclusion

It is necessary to legislate several provisions and professional requirements for self-regulatory communities:

1. To comply with ethical standards in scientific research, including biomedical studies. The development of molecular genetics, the decoding of the human genome, the establishment of genetic engineering and gene therapy quite expectedly take up the matter of moral, ethical and ethical-legal issues related to direct human intervention into the existence of living organisms. Thus, it is necessary to consider the correlation of state and public (in particular, self-regulation), the regulation of research, artificial selection and the accessibility of genetic engineering methods.

We should note that the state considers the uncontrolled use of genetic

engineering and synthetic biology technologies as a real biological threat.

2. To inform (both the population and medical community) through educational programs. The rapid development of sequencing technologies and the accumulation of genomic information have created a gap in the training of specialists in various fields of science and medicine. Doctors who underwent standard training, have medical qualifications and licenses do not have a sufficient level of competence to interpret genomic data.

3. To correlate genomic studies with good clinical practice and evidence-based medicine. The current results of genomic studies are based on scientific evidence but are still not sufficiently combined with the standards adopted in medicine. Today this rule is not obligatory but the new approach will be crucial at the stage of gene correction.

4. To present the study results of the human genome as personal data.

5. To distinguish between medical and non-medical activities in the field of genome.

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