GENOMIC RESEARCH LEGAL REGULATION SYSTEM: EXPERIENCE OF RUSSIA AND THE USA

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This article is devoted to the analysis of the genomic research legal regulation in the Russian Federation and the USA. In the United States, in addition to the legislation great importance is attached to medical and scientific institutions self-regulation, and such information is usually open. It is concluded that in Russia, despite the presence of both state and non-state scientific institutions engaged in genomic research, the mechanism of self-regulation as a whole is fragmented. It is also noted that Russia and the United States have specific legal regulation of these relations, which is reflected in the text of the article. For example, in the United States, unlike Russia, most organizations conducting genomic research, including genomic testing, are non-governmental.

Currently, the general trend in the legal regulation of genomic research in Russia and the USA is the active development of normative legal regulation. Moreover, a significant difference in the approaches of these countries is the active role of the US states in the development of regional legal regulation on these issues. Despite the fact that Russia is a federal state, the subjects of the Russian Federation are significantly limited in the genomic research legal regulation possibilities. This is largely due to both legal and political reasons that were given in this article. In the United States, a number of statutes have been adopted at the state level that regulate genomic research in such aspects as health insurance, confidential of personal information, the prohibition of discrimination, screening of newborns, and certain types of clinical and scientific research.

It should be noted that the genomic research regulation in the United States is not integrated into a single national consolidated act, which is a feature of this legal system.

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A comparative legal study of the fundamentals of legal regulation and self-regulation of genomic research in Russia and the USA made it possible to understand the specifics of regulation of these issues in different legal systems. The positive regulatory experience in conducting genomic research in the United States can be used to improve the regulatory framework of the Russian Federation in this area.

Key words: legal regulation, self-regulation, genetics, human genome, genomic research, human rights, Russia, USA

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INTRODUCTION

Genomic research is a relatively new area of science that emerged at the turn of the 1980s and 1990s and gained the rapid development of late because of the medical, biotechnological and informational improvement. As an interdisciplinary science genomics is aimed not so much at studying the development, structure, organization and behavior of individual genes as at studying the interaction of a set of genes in a given environment. Thus, genomic research is at the intersection of medicine, general biology, bioengineering, computer science and a number of other disciplines. The study of the genome of living organisms opens up great prospects for humanity, both in terms of treating and preventing previously incurable diseases, and in the field of gene family planning and bioengineering (Vasiliev, 2014:158). At the same time, genomic researching directly affects basic human rights (human dignity, privacy, health protection, etc.), therefore it requires strict observance and adoption of relevant documents. Being a comprehensive scientific industry, genomics studies the full spectrum of interactions between body genes: from the action of one gene on other genes and the genome as a whole, to the suppression of genes and the possibility of gene modification of a living organism. Genomics has a close relationship with ethics and jurisprudence, which is reflected both in the texts of regulatory legal acts and in codes of conduct for specialists and scientists conducting genomic research.

Modern genomic research carried out in most developed countries opens up previously inaccessible opportunities for modern society in the field of preventing and treating diseases, developing the latest methods of clinical diagnosis, combating epidemics, family planning, bioengineering and many other areas (Collins, Jegalian, 1999; Venter, Adams, Myers, Li, Mural, Sutton, Smith, Jandell, Rvans, Holt, 2001, etc.). So, for example, in the special scientific literature on the problems of genomic research, it is noted that a comparative analysis of the complete genomes of living beings is of great importance for understanding the heredity and variability of organisms, which allows us to draw conclusions that have general biological significance - about the mechanisms and rates of evolution, variability of genomes, etc. (Baltimore, 2001; Wolfsberg, McIntyre, Schuler, 2001; Snel, Bork, Huyten, 2000, etc.).

At the same time, the incessant development of social relations leads to the need for legislation improvement regulation. This statement is also true with respect
to the genomic researches, since this relatively new area of public relations combines both public and private interests. In this regard, normative legal regulation should take into account such principles as the balance of public and private interests, protection of human rights and freedoms, legally protected secrets, ensuring the national interests, etc. Thus, within the framework of various levels of legal regulation (state — federal and (or) regional, self-regulation — one or many relevant medical organizations or special associations that include these organizations), it is possible to consolidate special legal mechanisms to regulate the procedure for conducting genomic research ensuring its future development in accordance with the dynamics of social relations. However, when preparing such legislative changes, it is necessary to take into account possible economic, social, political and other consequences, since a high level of legal regulation implies a wide coverage of public relations affected as a result of such reforms.

The current situation in Russia in the field of genomic research, including normative legal regulation of this activity, demonstrates a number of trends, among which, first of all, it should be noted that Russia lags noticeably behind advanced foreign countries. So, in the Decree of the Government of the Russian Federation dated April 22, 2019 No. 479 “On approval of the Federal scientific and technical program for the genetic technologies development for 2019–2027”, in section I “Status of the genetic technologies development in the Russian Federation” it is officially stated that “the share of Russia in the total global market for the circulation of genetic technologies is critically small. Russian research and development in the field of genetic technologies does not yet allow to achieve large volumes of marketable results, as a result of which the products necessary for various industries are imported. Thus, the share of Russian imports of a number of amino acids (tryptophan, threonine, valine) used in the production of feed for farm animals reaches 100 percent, enzymes — more than 70 percent”. At the same time, it is necessary to note the desire of the Russian authorities to give greater normative certainty to various aspects of genomic research and, in general, to stimulate the development of genetics and genomics in the country.

However, at the moment there is no legal certainty in matters of legislative regulation of the nature, methods and standards of conducting genetic and genomic research in the country, the prevention and elimination of genetic discrimination, as well as maintaining the optimal balance between secret personal information and the possibilities of «open science». It can be concluded that Russia is moving towards the establishment of a comprehensive model of genomic research legal regulation.

LEGISLATIVE REGULATION AND FEDERAL STRATEGIC DOCUMENTS ON GENOMIC RESEARCH IN THE RUSSIAN FEDERATION

We can agree with the position that the main modern threats to the circulation of genomic information facing Russia include cost, unauthorized access, errors, mass screenings, irresponsible collection and irresponsible storage of genomic information.
(Dubov, Dyakov, 2019:136). Given that determining the position of one gene in the human genome is able to accurately identify one single person out of 10 billion other people, the implementation of genomic research poses certain tasks in the field of protecting personal data, privacy, medical, family and other secrets protected by law (Lin, Owen, Altman, 2004:183).

Speaking about the Russian experience in the legal regulation of the genomic research organization and conduct, it should be noted that in general this area has received fragmentary legal regulation. It comes down mainly to issues of state genomic registration (Federal Law of December 3, 2008 No. 242-FZ “On State Genomic Registration in the Russian Federation”), genetic engineering (Federal Law of July 5, 1996 No. 86-FZ “On state regulation in the field of genetic engineering activity”), genomic (genetic and molecular) examination (Article 79 of the Civil Procedure Code of the Russian Federation, paragraph 20 of the Resolution of the Plenum of the Supreme Court of the Russian Federation of May 16, 2017 No. 16 “On the application to the courts and legislation in cases involving the determination of the origin of children”).

Moreover, Federal Law of December 3, 2008 No. 242-ФЗ “On State Genomic Registration in the Russian Federation” defines the concept of “genomic information” as a type of personal data that includes encoded information about certain fragments of deoxyribonucleic acid of an individual or an unidentified corpse that do not characterize their physiological qualities. However, this concept is used only in the framework of the state genomic registration, and does not apply to other areas of the genomic information use, which is confirmed by the lack of relevant provisions in the legislation on personal data and law enforcement practice. In this regard, legal science expresses ideas about the need to amend this Federal Law in order to expand the scope of its action, in this case “it will have not only criminological, but also other goals, which, in turn, will force to establish a special regime of the genetic data use” (Romanovskaya, Romanovsky, 2013:44–45).

In Russian legal acts, as well as in judicial practice, human rights in genomic research are not defined, there are no necessary legal guarantees in this area, and the human genome is not currently considered an integral component of the right to protect health and medical care. In addition, in the Russian Federation the human genome is not the subject to civil rights; there are no special rules on criminal liability for criminal acts in the field of genomic research.

It should be noted the Federal Law of June 23, 2016 No. 180-FZ “On Biomedical Cellular Products”, which is aimed at the development, preclinical research, clinical research, examination, state registration, production, quality control, storing, transporting, importing into the Russian Federation, exporting from the Russian Federation, destroying biomedical cellular products intended for prevention, diagnosis and treatment of diseases or conditions of the patient, pregnancy maintenance, and medical rehabilitation of the patient, as well as the relations arising in connection with the donation of biological material for the production of biomedical cell products.

The Strategy for Scientific and Technological Development of the Russian Federation provided for several areas of development for 2019–2027 based on the genetic technologies development, such as: biosafety and ensuring technological independence; genetic technologies for agricultural development; genetic technologies for medicine; genetic technologies for industrial microbiology. The section of the Strategy on the state of genetic technologies development in the Russian Federation provides information on the significant lag in the domestic sphere of genetic technologies from advanced foreign countries in both scientific, regulatory, and applied aspects. It is also noted that in order to solve the problems of the genetic technologies development, it is necessary to create conditions for the formation of competitive scientific and (or) scientific and technical results, including an increase in the domestic laboratories number and research centers implementing engineering approaches, to prepare highly qualified research teams, to develop and create equipment and information resources to ensure their effective operation.

Despite the general strategic nature, the Program for the Development of Genetic Technologies for 2019–2027 contains a number of controversial statements. For example, it is indicated that the development of genetic technologies, including genomic editing technologies, and their practical application are priorities in leading countries of the world. However, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (concluded in Oviedo on April 4, 1997), which is currently not ratified by the Russian Federation and several other states, provides for certain legal guarantees for patients.

The fundamental principle of the 1997 Convention on Human Rights and Biomedicine is that intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only of its aim is not to introduce any modification in the genome of any descendants (Article 13). Thus, in the field of genetic research, a prohibition was established on intervention in the lives of future generations who did not give their consent (Montgomery, 2018:44–47).

In addition, in the mentioned Federal Program for the Development of Genetic Technologies for 2019–2027, on the one hand, it is rightly concluded that genomic
editing is a breakthrough tool that is already finding practical use in agriculture, industrial biotechnology, and medicine. On the other hand, Federal Law of July 3, 2016 No. 358-ФЗ “On Amending Certain Legislative Acts of the Russian Federation Regarding Improving State Regulation in the Field of Genetic Engineering” prohibited to import into the territory of the Russian Federation and to grow plants and animals whose genetic program has been modified using genetic engineering methods, except when this is done in the course of examinations or scientific research, and developers of the genetically modified products are required to undergo the relevant registration procedures. In the circumstances, the federal legislator needs to give a legal assessment of the current situation, taking into account the latest achievements of science, in particular genetic engineering, and the positions of scientists and specialists in the field of genetics, biology and jurisprudence.

At the level of the subjects of the Russian Federation (in contrast to the United States) there is no significant practice of normative legal regulation of genomic research. Russia is a federal state, where the subjects of the Russian Federation have a certain freedom within the established framework for the normative regulation of many issues of public life in accordance with Articles 71–73 of the Constitution of the Russian Federation. Despite the fact that there is no direct prohibition on the implementation of such regulation by the subjects of the Russian Federation, they apparently do not see any reason for the outrunning normative legal regulation on this issue. This is due to both the complexity and multidimensional nature of these public relations, which require an integrated approach and large time and labor resources, and the lack of any certainty from the federal center, which the regional authorities traditionally highly dependent on. Besides from a legal point of view, the subjects of the Russian Federation are limited by the Russian federal model which does not provide for a clearly fixed list of exclusive powers of the subjects of the Russian Federation. Articles 71 and 72 of the Constitution of the Russian Federation contains the exclusive powers of the Russian Federation and the joint powers of the Russian Federation and the subjects of the Russian Federation. In the second case, at the moment, the federal center has settled all the significant issues of joint jurisdiction; therefore, the subjects of the Russian Federation in the current realities can take extremely limited options for decisions, including in the field of legislative regulation. Although formally article 73 of the Constitution of Russia establishes the possibility of free regulation by the subjects of the Russian Federation of public relations not related to the jurisdiction of the Russian Federation or to the joint conduct of the Russian Federation and the subjects of the Russian Federation, but in fact there are practically no such issues or they are insignificant.

There is also the problem of genomic research self-regulation in Russia, or rather the practical absence of this mechanism in domestic practice. So, despite the fact that in the Russian Federation there is a number of well-known federal state budgetary scientific institutions that have been working for a long time (Federal State Budgetary Scientific Institution “Research Centre for Medical Genetics” (RCMG), The
Vavilov Institute of General Genetics (VIGG) of the Russian Academy of Sciences, The Federal Research Center Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences, etc.), an extremely small amount of information can be found in the public domain in the field of development and adoption of documents on the ethical issues regulation, on the strategic regulation, etc. (except for joint research and participation in scientific events). These scientific institutions, in the framework of their activities, are obliged to fulfill the state task, receive appropriate funding from the budget of the Russian Federation, and must also perform work that may be associated with state secrets. Thus, the activities of these scientific institutions are closely related and largely aimed at implementing state policy in the field of biomedical research, including genetic research.

Moreover, each such state institution has its own specifics, which requires a separate legal study. For example, a number of documents were approved and made publicly available at the Federal State Budgetary Scientific Institution “Research Centre for Medical Genetics” (RCMG), unlike other state scientific institutions of a similar profile, with regard to the functioning of the ethics committee, work with confidential information, and also the procedure for considering citizens' appeals. Thus, by Order No. 2/16 of January 11, 2016, the Federal State Budgetary Scientific Institution “Research Centre for Medical Genetics” (RCMG) adopted the standard operating procedures of the local ethics committee in accordance with the requirements of the legislation to ensure independent examination, consultation and decision-making on biomedical research ethics involving people and/or animals. In addition, on August 28, 2017, only the Research Centre for Medical Genetics (RCMG) approved the Regulation on Confidential Information in Clinical Trials of Medicines, which generally regulates the procedure for working with various types of confidential information (official information, trade secret, medical secret, state secret) to ensure the economic and legal security of this institution during the clinical trials of medicines.

A development program (for 2016–2020) has been adopted and made publicly available on the official website on the Internet at the Federal Research Center Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences, despite the fact that the opportunity to develop and approve such programs is provided for by all considered institutions (most likely, these documents have the limited use status, as they can be associated with official information and state secrets).

In Russia, a number of non-state companies carry out activities in the field of genetic research, primarily genomic testing. Companies on their official sites on the Internet indicate that genetic tests will allow you to: decrypt the human genome, learn about ancestors, get tips on playing sports, weight loss and nutritional advice, and warn about addictions to diseases. However, analysis of open information sources does not allow finding any self-regulatory documents of non-governmental institutions, unlike state ones. We believe that this is due both to the weak level of development of these public relations in the country, and to the lack of appropriate legislative regulation.
Based on the information above we can conclude that the legislation of the Russian Federation in the field of genomic research is at the initial stage, which is not surprising given the relative youth of this field of science. For the development of genetics, the noted federal strategic documents are adopted, which, most likely, will form the basis for further legislative regulation of genomic research in the Russian Federation. The legal regulation of genomic research and genetics in general in Russia, according to the aforementioned and a number of other state documents\(^2\), should receive an active impetus for development in the coming years (Mokhov, 2019; Vasilev, Osavelyuk, Burtev, Suvorov, Sarmanaev, Shirokov, 2019, etc.). However, the unstable foreign policy situation is a risk and a big challenge for Russia, in particular, associated with some restrictions on the import of certain foreign products into Russia. This may negatively affect the noted plans for intensive progress in the field under consideration and, with a high degree of probability, will interfere with improvement of new research methods and practices for conducting genomic research in Russia.

**LEGISLATIVE REGULATION ON GENOMIC RESEARCH IN THE UNITED STATES OF AMERICA**

The US legislation and by-law regulations in the field of genomic research are also not complete enough, but they have certain characteristic features (Branum, Wolf, 2015:579–588). As the researchers note genomic research is becoming more international, cross-border cooperation and data exchange are developing, and although different legal systems, precedents and cultural values exist in different countries, international harmonization of genomics policies is instrumental in cooperation and development of research in this area (Branum, Wolf, 2015:579–588; Lévesque, Joly, Simard, 2011:583–589).

Attention should also be paid to such a debatable issue as the provision of the genetic or genomic results to third parties, in particular to relatives (Zawati, Knoppers, 2012; Lévesque, Joly, Simard, 2011; Zawati, Van Ness, Knoppers, 2012; Knoppers, Dam, 2011, etc.). In the United States, the implementation of genomic research has a close relationship with the information legal regime: on the one hand, the genomic research requires the transfer of research data for the science development, and on the other hand, the transfer of research data should not jeopardize personal, family and other types of secrets. Current U.S. law to protect information from disclosure does not prohibit the transfer of data from genomic research to third parties or other countries. According to US laws and regulations, the results of genetic or gen-

nomic studies can be shared with relatives in several ways (Branum, Wolf, 2015:579–589). The easiest way for relatives to access such research results is to receive it from the patient with his consent. Relatives can also get the results of these studies directly from the researchers, if the participant has previously agreed to this type of exchange. In addition to these two situations, a number of states have confidentiality laws regarding genetic testing that may be relevant to sharing genomic research results with relatives. For example, in South Carolina, there is a law on the exchange of human genetic information in families after his death, not paying attention to research results. At the federal level, the exchange of genetic research results is regulated by the Confidentiality Act and regulations issued by the Federal Civil Rights Office in accordance with the confidentiality clause set out in the Health Insurance Mobility and Accountability Act (HIPAA) (Branum, Wolf, 2015:583–585).

The United States National Institutes of Health (NIH) adopts regulations designed to ensure the transfer of anonymous information for research purposes based on the principle of medical information secrecy3. In addition, NIH has several databases that can be supplemented with de-identified genomic research results, and US research institutions can also access these databases.

It should be noted that there is a large-scale project supervised by the NIH, the meaning of which is to create a national genomic database. Starting in 2018, U.S. citizens will be invited to volunteer to contribute to the huge new array of genomic information collected by the government, a project that is positioned as a promising event within the new frontier of gene medicine4. This program, first launched in test mode under US President Barack Obama, aims to essentially assemble the world's largest genetic library, designed for wide access by scientists and researchers5. This collection of DNA information from US citizens is essential in order to help scientists and researchers to study the genetic basis for all types of health conditions, as well as for those working on the development of targeted treatment methods adapted to the individual’s genetic structure6.

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NIH’s responsibilities also include control of access to sensitive information, and information that can identify a specific person by genome. Until 2014, U.S. law permitted the collection of blood samples from newborns during screening without the consent of their parents, which led to numerous complaints and lawsuits from citizens, and ultimately led to the need to destroy about 5 million samples taken in Texas. The US Congress, passing the Law on the Redistribution of Authority in the Field of Newborn Screening in 2014, put an end to the issue of taking samples from newborns for the purpose of genomic research and decided that such actions can be considered legal only with the consent of the parents7.

In 2008, the United States passed the Law prohibiting discrimination based on genetic information (Genetic Information Nondiscrimination Act (GINA))8. This Act aims to protect US citizens from discrimination based on genetic information in the areas of health insurance and employment (Tavani, 2004; Otlowski, Taylor, Bombard, 2012; Baruch, Hudson, 2008, etc.). The first part of the Law (medical insurance) prohibits medical insurance companies from using the results of genetic and genomic research to decide on eligibility, insurance coverage, and the purpose of making insurance payments to the insured citizen. In addition, medical insurance companies are not entitled under the Law to require the client to undergo genetic testing or provide genetic information (which includes, among other things, the medical history of the client and information about the presence of genetic diseases in his relatives). The second part of the Law prohibits employers from using the results of genetic and genomic research in making decisions such as employment, dismissal, promotion, setting salaries. In addition, the Law prohibits employers from requiring an employee (applicant) to undergo a genetic test or to submit the results of genetic or genomic studies.

GINA also includes a number of provisions on the genetic and genomic clinical trials. These provisions mainly concern the issues of informed voluntary consent of the patient to participate in research and to process information obtained from their results. So, in particular, GINA stipulates the obligation of organizations conducting genomic and genetic research to inform patients about the risks associated with the collection and further processing of the obtained data, and also to inform them how their confidentiality will be ensured. In order to develop the regulatory requirements of GINA, the Office for the Protection of Human Research has developed guidelines for the implementation of GINA in the clinical trial process9.

In the scientific literature, it is noted that although GINA is a generally progressive legislative act, however, this Law has encountered a number of problems in terms of its practical use (Lefebvre, 2015:31). In particular, it is pointed out that, despite all the efforts of lawmakers to provide patients with greater protection, these mechanisms will be effective only when they become widely known. To empower patients, they should be provided with educational resources so that they can better understand the risks associated with confidentiality associated with the disclosure of their genetic information, both for themselves and their relatives.

Also there is a number of other US laws related to the genomic information regulation like the Health Insurance Portability and Accountability Act of 1996 (HIPAA)). According to the amendments to this Law of 2013 genetic information is considered medical information, therefore, insurers cannot use it to make any decisions regarding health insurance benefits, eligibility for benefits or calculation of insurance premiums under the health insurance plan.

The Patient Protection and Affordable Care Act (ACA) of 2010 introduced the obligation for US citizens to get medical insurance if they don’t have it yet. The Act also prohibited health insurance issuers from discriminating against patients with genetic diseases, denying them coverage due to pre-existing conditions. In addition, the ACA provides additional protection for patients with genetic diseases by stating that certain insurers may vary premiums only depending on a few established factors, such as age or geographic area, thereby prohibiting any adjustment to premiums due to any medical conditions.

The Americans with Disabilities Act of 1990 (ADA) prohibits discrimination in employment, public services, housing, and communications based on disability. In 1995, the Equal Employment Opportunity Commission (EEOC) published an interpretation that ADA prohibits discrimination based on genetic information about a disease, illness, or other disorder. However, these opinions of the EEOC are not legally binding, and the question of whether the ADA protects against genetic discrimination in the workplace has not yet been considered in court. In doing so, ADA was used by the employer to challenge the practice of genetic testing. So, in 2001, the EEOC filed a lawsuit against the Burlington North Santa Fe Railway (BNSF) for covertly testing its employees for a rare genetic condition (HNPP) that causes carpal tunnel syndrome as one of its many symptoms. The BNSF argued that testing was a way of determining whether there was a high rate of injury from recurring work-related stress among its employees. In addition to testing for HNPP, company-paid

doctors were also instructed to check some other diseases, such as diabetes and alcoholism. EEOC and BNSF announce dispute resolution through mediation in 200212.

There also are many laws of several US states in the field of citizen protection from genetic discrimination, which differ significantly in the applicability and scope of protection provided13. GINA sets a minimum level of protection against genetic discrimination and does not limit US state laws to stricter protection measures. The first laws at the state level of the USA concerned, first of all, the specific genetic conditions for the implementation of certain activities. For example, North Carolina was the first state to prohibit sickle cell anemia discrimination. In 1991, Wisconsin was the first state to prevent discrimination in the implementation of genetic tests. Currently, 48 states and the District of Columbia have passed laws prohibiting genetic discrimination among health insurance providers. However, Mississippi and Washington have not passed laws prohibiting genetic discrimination in the field of health insurance. 35 US states and the District of Columbia prevent genetic discrimination in employment. Some US states have laws that go beyond the GINA framework and prohibit genetic discrimination for other types of insurance, including life insurance, disability insurance, and long-term care insurance14. In 2011, California adopted the California Non-Discrimination Act on Genetic Information (CalGINA), which further expanded the protection of citizen rights to prohibit genetic discrimination in emergency care, housing, mortgage lending, education and in other government-funded programs. There are currently laws in 17 states that restrict the use of genetic information when determining coverage for life insurance, in 17 states for disability insurance, and in eight states for long-term care insurance15.

Despite a certain fragmentation of the US regulatory framework in the field of genomic research, individual US government bodies and organizations strive to develop their own acts of both federal and regional significance, which would make it possible to bring greater clarity to the regulation of genomic research. At the federal level, the role of bodies such as the Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS) should be noted. Some time ago, the US Federal Trade Commission was empowered to prosecute companies involved in genetic and genomic research for posting advertising information that does not match the actual characteristics of the services; however, today the role of the Commission in regulating genomic research is minimized.

The regulatory acts developed by the Food and Drug Administration and the Center for Medicare and Medicaid Services are based on three main criteria for genetic and genomic research: analytical validity, clinical validity, and clinical utility\textsuperscript{16}. Analytical validity allows us to give the most accurate answer to questions such as: how well the test predicts the presence or absence of a particular gene or genetic change. Can the test consistently and accurately detect whether a specific genetic variant is present or absent? Clinical validity refers to how well the genetic variant(s) being analyzed is related to the presence, absence, or risk of a specific disease. Has having a specific genetic variant been conclusively shown to increase the risk or likelihood of having a disease or eventually developing a disease? Clinical utility refers to whether the test can provide information about diagnosis, treatment, management, or prevention of a disease that will be helpful to patients and their providers. Will use of the test lead to improved health outcomes?

The Center for Medicare and Medicaid Services, within the framework of its authority, adopts regulatory acts aimed at monitoring the analytical validity of genetic and genomic studies, but there are no regulations at the federal level that would regulate the mechanism for monitoring the clinical validity of research. The control mechanism itself is actually also absent. In this regard, the Food and Drug Administration is currently developing a new policy aimed at regulating the analytical validity of genetic and genomic research, as well as expanding overall supervision of the clinical relevance of research. So far the Office has not adopted a single official action plan in the framework of the issue under consideration, however, it collects information on successful research in the field of genetics and genomics, which should subsequently play an important role in the development of common standards for genetic and genomic research on national level.

The Center for Medicare and Medicaid Services indirectly regulates the activities of clinical laboratories through the CLIA program — Clinical Laboratory Improvement Amendments, which established the requirements for certification of laboratories conducting genetic and genomic research. The CLIA program appeals to the analytical validity of genetic and genomic studies, but does not in any way regulate the clinical validity of studies. In this regard, the Food and Drug Administration controls enforcement discretion for organizations conducting genetic and genomic research. Enforcement discretion allows the Office if necessary to regulate genetic and genomic research directly and at its own discretion. In the understanding of the Office, genomic and genetic studies are equated with medical technologies, while the Office has the right to determine what methods and mechanisms for carrying out genomic and genetic studies are entitled to appear on the market — thus, all manufacturers of genomic and genetic technologies, reagents, research mechanisms, and the

corresponding equipment is required to obtain the consent of the management before placing products on the market.

Currently, in the United States there is a tendency towards a gradual rejection of discretionary powers in favor of direct strict regulation for conducting genomic research, which is not surprising - the extremely rapid growth of genomic technologies can create certain threats to public welfare and public health. Being poorly regulated, genomic research can get out of control, which is fraught with multiple problems both in the field of law and in human biology. Aware of the potential dangers of unresolved genomic research, the Food and Drug Administration has developed a series of documents to modernize public policy on genomic research. These include the 2014 Laboratory Test Oversight Framework Guide, the 2018 New Generation Test Guide, the Manufacturers, the 2014 Office Staff and Clinical Laboratories Notification Guide for Laboratory Tests.

In this regard, we cannot fully agree with those who believe that unlike many European states the United States has a clear advantage, because they do not have any national barriers or different regulatory frameworks to overcome it (Sakhipgareeva, 2019:148).

The above and other documents developed by the Food and Drug Administration alone or with the assistance of other government bodies and organizations are not mandatory, but they allow us to trace the intentions of the American public administration to normatively enforce rules that would fully regulate genomic research in the country.

CONCLUSION

Based on the genomic research legal regulation analysis in the Russian Federation and in the USA, the following conclusions can be drawn.

1. In the United States there is no single special legal act that would fully regulate the organization and conduct of genomic research. At the same time, these issues are sufficiently covered by a number of related legal acts (on the protection of personal data, prohibition of genetic discrimination, provision of genetic testing services, etc.). Despite such a certain fragmentation of the US regulation in the field of genomic research, individual government bodies and organizations are striving to develop their own rules that would provide for greater clarity in the genomic research regulation. Accordingly, the self-regulation of genetic and genomic research, that is, the adoption of legal and ethical documents by relevant medical organizations, plays an important role in these processes. This kind of practice has not been significantly developed in Russia at present, due to the low level of legal regulation of genomic research in the country. Thus, the Russian legislator has the opportunity to choose the model of genomic research legal regulation: the adoption of a single consolidated legal document, or amending many legal acts affecting various aspects of the genomic research.
2. The US trend in this area is the adoption of legal documents, standards and rules aimed at additional regulation of the genomic research at various levels of public authority and organizations. This trend indicates certain deficiency in legal regulation at present, as well as understanding of the special importance of this area, which requires constant legal monitoring, regulatory and organizational improvement. In this regard, it is advisable for Russian lawyers and lawmakers to consider the possibility of using some regulatory and ethical approaches to the genomic research legal regulation, including oversight powers to the relevant public authority.

3. The United States provide a range of legal guarantees for citizens in the field of genomic research. This relates to the obligation to preserve genomic information, the prohibition of its unauthorized transfer and use (in this case, there is a certain discretion at the national and state levels), as well as the protection of citizens from genetic discrimination, which primarily occurs in labor relations and the field of human insurance. The standards for conducting genetic and genomic research are designed to overcome the deficiency of legal regulation in this sphere, since genomic research can get out of control, which is dangerous by multiple problems in law, ethics and human biology.

4. In general, in Russia, unlike the United States, self-regulation of genomic information activities is extremely poorly developed. The charters of institutions that operate with genomic information only contain general issues of a legal, financial nature. Usually there are no provisions directly regulating the rights, obligations, legal liability, guarantees of participants in genetic studies. At the same time, they consolidate areas of activity in the field of genetic research, the main responsibilities under the jurisdiction of federal state bodies, as well as ethics committees are created, codes of ethics are adopted.

A different situation can be observed with non-governmental organizations. They usually do not accept ethical codes, documents containing genomic research regulation. This indicates the great freedom of non-governmental institutions in organizing genetic research, denial of publicity in the activities of these companies in terms of self-regulation and the development of ethical standards for genetic research. There are no ethical committees, no mention of following any European or international ethical rules. At the same time, this indicates possible violations of human rights in terms of ensuring the preservation of genetic information, ensuring the consent of a person to medical manipulations with human biomaterials, protection against arbitrary editing of the human genome or its transfer to third parties without the consent of the patient, etc.

5. In Russia, the legal regulation of genomic research currently consists of bylaws, primarily the decrees of the President of the Russian Federation. This is due to the possibility of the decrees of President of the Russian Federation to regulate public relations that have not received the relevant regulation by federal law provided for in article 90 of the Constitution of the Russian Federation (Decree of the Constitutional Court of the Russian Federation of April 30, 1996 No. 11-P). The considered
sphere of public life, affecting human rights issues, protection of personal data, intellectual property, as well as the strategic development of domestic science should be stated in a special federal law. At the same time, it is impossible to ignore the possibilities of regulating certain aspects of genomic research by the subjects of the Russian Federation, which is justified both from the point of view of federalism and the need to take into account the cultural, national, socio-economic and other specifics of each subject of the Russian Federation.

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В статье представлен анализ правового регулирования проведения геномных исследований в Российской Федерации и США. Отмечается, что в США, помимо соответствующего законодательного регулирования данных отношений, большое значение придается саморегулированию соответствующим медицинским и научным учреждениям, и такая информация, как правило, носит открытый характер. Делается вывод, что в России, несмотря на наличие как государственных, так и негосударственных научных учреждений, осуществляющих геномные исследования, механизм саморегулирования в целом носит фрагментарный характер. Также отмечается, что Россия и США имеют специфику правового регулирования данных отношений, что получило свое отражение в тексте статьи. Так, в США большинство организаций, осуществляющих геномные исследования, в том числе геномные тестирования, является негосударственными, в отличие от России.

В настоящее время общей тенденцией правового регулирования геномных исследований в России и США является активная разработка нормативного правового регулирования отмеченной области общественных отношений. При этом существенным различием подходов данных стран является активная роль штатов США в разработке регионального правового регулирования по данным вопросам. Несмотря на то, что Россия является федеративным государством, субъекты Российской Федерации в значительной степени ограничены в возможностях осуществления правового регулирования многих аспектов проведения геномных исследований. Это связано во многом как с правовыми, так и с политическими причинами, которые были приведены в данной статье.

В США на уровне штатов принят ряд статутов, регулирующих применительно к геномных исследованиям такие вопросы, как медицинское страхование, конфиденциальность персональной информации, запрет дискриминации, осуществление скрининга новорожденных, а также проведение отдельных видов клинических и научных исследований.

Следует отметить, что вопросы регулирования геномных исследований в США не объединены в какой-либо единый национальный консолидированный акт, что является особенностью указанной правовой системы.

Сравнительно-правовое исследование основ правового регулирования и саморегулирования геномных исследований в России и США позволило понять специфику регулирования данных вопросов в отмеченных правовых системах. Позитивный опыт нормативного регулирования проведения геномных исследований в США может быть использован в целях совершенствования нормативной правовой базы Российской Федерации в рассматриваемой области.

**Ключевые слова:** правовое регулирование, саморегулирование, генетика, геном человечка, геномные исследования, права человека, Россия, США

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