

# Principles of Correlation Between Self-Regulation and State Legal Regulation of the Relations Related to Genetic Research: Modern Prospects



Ksenia V. Mashkova, Maria Viktorovna Varlen, Sergey Sergeevich Zenin, Anri Lvovich Bartsits, George N. Suvorov

**Abstract:** *The principles of correlation between self-regulation and state legal regulation of the relations related to genetic research have been discussed in this article. Today the development of genetics and applied genomic medicine has a direct effect on legal relations on protecting the rights and legal interests of an individual. The main goal of the study is to research regulatory legal acts, judicial practice, and doctrinal sources aimed at determining the optimal correlation of the beginnings of self-regulation and state legal regulation of relations related to genetic research. When writing the article, the methods of collecting and studying singularities, the generalization methods, the scientific abstraction methods, as well as the method of inquiry into regularities have been used. This study is characterized by using the experience of foreign self-regulatory organizations and professional associations involved in genetics. In their study, for the first time, the authors have substantiated the conclusion that the model of the optimal correlation of state regulation and self-regulation of legal relations related to genetic research is based on the following principles: 1) informed consent for genetic research and protection of the confidentiality of the obtained information, 2) participation of self-regulating associations of medical geneticists in developing national standards for the quality of medical services in genetic research, as well as the requirements for medical organizations and medical employees who provide them, and 3) legalization of the legal status of a person providing counseling services in genetic research and in associated areas related to defining a strategy for the treatment of genetically determined diseases and the use of assisted reproductive technologies (genetic counselors). In the article it has also been stated that it is necessary to define the legal mode of protecting the information obtained during the genetic research depending on classifying such research as a certain specific category – diagnostic, pre-symptom or prognostic (carried out to*

*assess the vulnerability of an individual to a specific disease). Third parties can only access the results of diagnostic genetic research.*

**Index Terms:** *principles, gene diagnostics, gene therapy, protection of information, legal status, genetics.*

## I. INTRODUCTION

Today the development of genetics and applied genomic medicine is associated with gene diagnostics and gene therapy that have a direct effect on legal relations on protecting the rights and legal interests of an individual.

Gene diagnosis is associated with genetic testing or a comprehensive research of the human genome in order to identify significant, genetically determined peculiarities or characteristics. Genetic research and personal genomic testing gradually become popular services provided by commercial medical organizations. This type of research and testing enables individuals to access a wide range of information that can be used for family planning, treating hereditary and other genetic diseases, lifestyle changes to improve health and other purposes. In general, the results of genetic research can be used in the following main areas: 1) to identify the predisposition to certain genetically determined diseases, assess risks of their occurrence and predict future treatment and preventive measures, 2) for family planning when applying assisted reproductive technologies, 3) for a comprehensive assessment of risks in voluntary personal insurance, as well as employment risks, and 4) for further scientific research.

The area of genetic research is wide and can cover both adults and minors, as well as the unborn [1]. Mass screening of the entire adult population, the creation of a genetic passport of every citizen can cause misuse [2]. The evidence from practice shows that credit, insurance companies, and employers are the most interested in obtaining genetic information [3]. Banks can create an additional safety mechanism when providing long-term loans to those citizens who have a predisposition to certain diseases. An employer can set barriers to employment and refuse the job seekers who may have a predisposition to certain occupational diseases [4].

**Revised Manuscript Received on 30 July 2019.**

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Services on genetic research and personal genomic testing become more and more available in terms of improving medical technology and pricing policy, which also has impact on their increasing popularity.

At the same time, the provision of services on genetic research and personal genomic testing to a wide range of consumers allows accumulating an unprecedented volume of genetic data, which, on the one hand, creates the basis for further scientific research, and on the other hand, makes think about the legal mode of such information, self-regulation, and the need in the government participation in the provision of medical services related to genetics in order to protect the citizens' rights and legal interests.

## II. LITERATURE REVIEW

This study used the works of famous researchers who devoted their findings to the legal regulation of genetic developments. Romanovsky G.B. considered the legal regulation of genetic research in Russia and abroad. Geller, G., Rushton, and Cynda [5] studied the experience of specialists in the area of genetics and the legal regulation of this area. Paola Bin, Adelaide Conti, Emanuele Capasso, Piergiorgiofedeli, Fabio Polichino, Claudia Casella, Paola Delbón, Vincenzo Graziano dealt with the issues of genetic testing and legislative regulation of this area. The work of Shade, Jess I. Kuhn, Hilary I. Doherty, Anna [6] about ethical consequences of using biobanks and population databases for genetic research of suicides is of great interest. Many experts studied this topic, but the development of principles related to the correlation between the government regulation and self-regulation of legal relations in the area of genetic research has not been studied and requires a comprehensive analysis because the principles of the correlation between government regulation and self-regulation in the area of genetic development will allow to regulate these legal relations when the legislation in this area has been underdeveloped.

## III. METHODS

### A. General Description

Methodologically the study is based on general philosophical (materialistic and dialectical), general scientific (historical, logical, system-structural, axiological), particular scientific (specifically sociological, statistical, hermeneutical, modeling, strategic assessment method), and special (structural-legal, comparative legal, and formal legal) methods. In this article the use of the axiological (value) method that involves a comprehensive analysis of the above public relations in terms of moral, ethical and social values is emphasized. The problems of legal and ethical regulation of genetic research are studied in terms of their impact on social processes, provision of a reasonable balance of interests of a certain individual and the public health care, development of the area of genetic services (genetic and genomic research, genetic counseling), and improvement of the technologies used in them in general. The comparative legal method is as important. It aims at obtaining objective information that makes it possible to make a wider use of the positive

experience of other countries, as well as professional associations of geneticists found in them, taking into account its understanding and adaptation to the Russian conditions. When applying the comparative legal method, it was presumed to comply with the following principles: comparability, i.e., the relative similarity of the phenomena and processes under research; equivalence of concepts and procedures used in the study; universality involving the study of legal processes and phenomena, taking into account the common cultural-historical contexts; and reliability of interpretation of legal processes and phenomena implying peculiarities of the cultural and historical context. In this article, based on the system-structural and formal-legal methods, regulatory legal acts, judicial practice, ethical rules, and quality standards of medical services of professional associations of geneticists are comprehensively analyzed. This analysis aims at defining principles of the optimal correlation of state legal regulation and self-regulation of public relations related to genetic research.

### B. Algorithm

The following research methods are used as auxiliary ones:

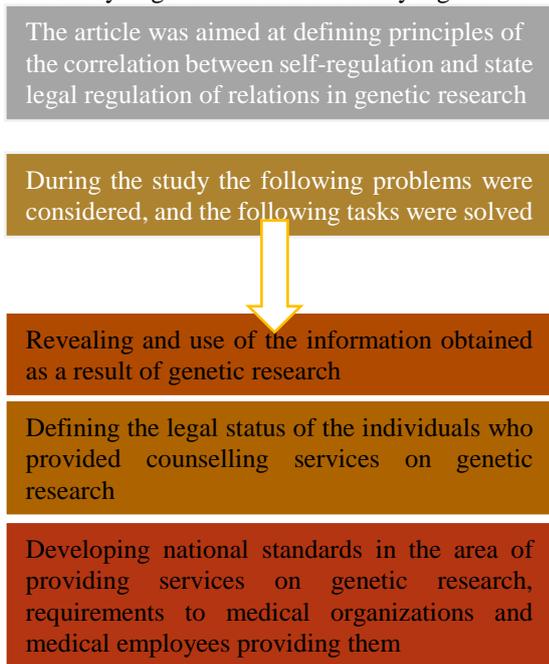
1. The method of participant observation that involves the inside analysis of the situation under study from the actor point of view (consumer of genetic services, genetic counselor, other participants in legal relations in the area of genetic research). As for this study, the method of participant observation is used when consistently considering legal norms, taking into account legal practice, organizational and legal aspects of the activity performed by professional associations, self-regulatory organizations of geneticists. Thus, the optimal model of the correlation of state regulation and self-regulation in the genetic research is created, developed and verified by systematically collecting and analyzing the data related to the phenomenon under study.

2. The method of monographic description of a case (object) in the maximum number of its interrelations (case study). In this article, it is used to analyze legal phenomena that cannot be generalized in terms of quantity, but have a heuristic value for the purpose of identifying and studying the regularities of developing the system of state and local regulation of genetic research. This method makes it possible to consider peculiarities of the organization and activities of certain professional associations, self-regulatory organizations of geneticists, examples of solving certain ethical and legal problems in the area of genetic research.

3. The method of legally significant typifications that makes it possible to extend the positive experience of state legal and local regulation of genetic research relations in a number of countries to new types of public relations in this area that are actualized due to the development of technical progress. Using the method of legally significant typifications, it is possible to make up a legal basis for organizing and carrying out genetic testing and complex genomic research that regulates the mechanisms for protecting the citizens' rights and legal interests, which is a prerequisite for the development of the area of genetic research, as a whole.

**C. Flow Chart**

In the study, certain algorithms were used to obtain results. Figure 1. Study Algorithm shows the study algorithm.



**Fig. 1:** Study Algorithm

**IV. RESULTS**

The problem of searching for an optimal correlation of state regulation and self-regulation in genetic research is revealed in relation to the following blocks of issues whose regulation at various levels in aggregate determines the national legal regime for genetic research.

*Revealing and use of the information obtained as a result of genetic research (genetic testing, genomic research).*

The European Society of Human Genetics (ESHG) adheres to the “right not to know” about the genetic information related to the examined individual [7]. Such right is recognized mainly in the cases when the genetic predisposition to certain diseases does not mean the imminent emergence and development of any of them in the future, as well as in the cases when during the period of time between the test and preparation of its results there can be circumstances that will make the interested person refuse from obtaining the information about the results of genetic research. Thus, according to the ESHG, if the “right not to know” is based on the principle of autonomy, it is considered a means of protecting the patient’s psychological integrity, and should be protected if the right is clearly expressed by the interested person [8].

The interpretation of the concept “genetic data” is extremely broad. This is how results of genetic tests and any other information that, regardless of its type, identify the individual’s genotypic characteristics that can be inherited in the relevant related group, as well as the “genetic test” itself are considered as an analysis made for clinical purposes with respect to the DNA components for making or confirming a diagnosis (a diagnostic test), identifying or excluding the mutation associated with a genetic disease a healthy person may have (a pre-symptom test), and assessing the individual’s susceptibility to a certain disease (a prediction or

susceptibility test) (Universal Declaration on the Human Genome and Human Rights).

In Italy, genetic data can be processed and used as biological samples if the goals on protecting public health cannot be achieved in each certain case by depersonification of the obtained information or samples for

a. Protecting the health of citizens, taking into account the specifics of genetic diseases and protecting the genetic identity of the data subject, subject to the consent of the data subject,

b. Protecting the health of citizens, taking into account the specifics of genetic diseases and protecting the genetic identity of a third party belonging to the same genetic (related) line as the data subject, subject to the consent of the data subject, and

c. Science in terms of the scientific and statistical research aimed at protecting the health of the data subject, third parties and the community in the medical, biomedical and epidemiological sense, including clinical investigation of medicines, as well as scientific research aimed at developing methods for genetic analysis [9].

It is necessary to take into account the fact that if the consent to use the results of genetic research was not or cannot be provided due to the disability, health status or mental disability of the data subject, or because it is impossible to determine the location of the latter, the genetic data can be processed taking into account the available information.

It is interesting that the permission to access genetic data is granted to judicial experts, private detective agencies, and judicial representatives to prove the claims made in court, regardless of whether the subject is related to relatives of the third party. The cases when the processing of genetic data requires additional genetic tests are an exception. For public purposes, the permission to process personal data is granted solely to enable authorized persons to fulfill certain obligations and ensure the fulfillment of such obligations provided for by the legislation regulating public health and hygiene, prevention of occupational diseases, their diagnosis and treatment, including transfusion of blood and organs, transplantation of tissue and hematopoietic stem cells, rehabilitation of physical and mental pathologies and disorders, protection of mental health, and pharmaceutical care. It is permitted to process genetic data and use biological samples for pre-symptomatic tests and tests for susceptibility to certain diseases only in order to achieve health care goals, including the conscious choice of the reproductive function and research objectives related to the protection of public health. In Portugal, Law No. 12/2005 dated January 26, 2005 on personal genetic and other medical information contains the provisions on the medical information and medical records, and obliges the hospital physician to enter the results of genetic research into the automated database. At the same time, the protection of personal data is guaranteed by the constitution. Due to this, third parties can access genetic information only in case of its depersonification, as well as for static processing.

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The legal relations in the area of genetic research are also subject to general norms on the medical secrecy protection [10]. The Greek legislator's approach is of great interest. Here a medical employee is prohibited to disclose information about the results of genetic research obtained, including from the patient or other sources. Thus, genetic testing issues are mainly regulated by the legal framework applied in the Greek national health system, as a whole (European Ethical-Legal Papers N°6 Patient Rights in Greece). It is possible to see that the restriction of the principle of confidentiality of the genetic research results is considered justified in most jurisdictions provided that it is necessary to protect the rights and legal interests of third parties or public health.

*Developing national standards for services on genetic research, requirements to medical organizations and medical employees that provide them.* In the modern world practice, there are rather many illustrative examples when there is no state regulation and national standards for services on genetic research are developed by professional associations of geneticists and self-regulatory organizations [11]. At the same time, the impact of such associations and organizations on the regulation of the professional activities of the specialists involved in genetic research is determinant.

For example, the American Board of Medical Genetics and Genomics (ABMGG) states the following goals of its activity: the promotion of the quality standards for medical services in genetic research, the unification of the association of specialists in genetics, and public awareness of the procedure and terms and conditions for genetic testing and genetic research. The professional association carries out its powers in three main areas: 1) it ensures the compliance with generally accepted standards of medical care, avoidance and resolution of conflicts on the quality of medical services provided in the area of genetic research between doctors and patients, 2) it develops and implements standards of the professional ethics in relations with patients and colleagues, distributes knowledge about the nature and importance of genetic research, and 3) it organizes the accreditation, qualifying examination and certification of medical employees engaged in genetic research. The compliance with the quality standards of medical care remains a top priority even if the norms of federal laws, state laws, and requirements of employers or other persons do not meet the interests of patients or clients. Having identified such contradictions, geneticists should be able to carry out the necessary laboratory studies, including the full range of services sufficient to meet the relevant service standards [12]. It has been prohibited to take tests, examine or treat if this is not determined by the set task, and is not justified in terms of the quality standard of medical care [13]. The objectives of the council are the following: 1) to contribute to developing, stimulating and promoting genetic research and clinical genetics, 2) to develop education, research and innovations in the area of clinical genetics and genomics, 3) to contribute to the public awareness of the achievements of modern genetics and genomics in the fight against hereditary diseases and in the area of reproductive technologies, 4) to support specialists contributing to the development of genetics and genomics in health care organizations, 5) to prepare expert opinions on the issues of public interest in the area of genetics and genomics,

and 6) to cooperate with other national and international professional communities that promote the study and practical application of the achievements of genetics and genomics. It is possible to see that the participation of the professional association of geneticists in the development of national standards for services on genetic research, requirements for medical organizations and medical employees that provide them depends on the principles the professional association of specialists in genetics is organized in a particular state. These principles also determine the solution of the problem on determining the legal status of representatives of the new "profession" that emerged in the world due to improving the technology of genetic research – these are the so-called "genetic counselors".

*Defining the legal status of the individuals providing counseling services in the area of genetic research.* It is necessary to bear in mind that in a broad sense genetic diagnosis is a process consisting of at least three stages: informing about the upcoming research and its possible results, the degree of their reliability; sampling and direct research in the laboratory; informing and interpreting the results, and counseling on further therapeutic and preventive measures. The work in the genetics does not end in the laboratory because it is mainly related to the process of interaction between the geneticist and the patient, from offering to carry out a research to counseling services [14].

It is possible to speak about the following main tasks of genetic counseling: 1) a comprehensive analysis and comparison of the results of genetic and genomic tests, the results of other medical research to assess the probability or recurrence of a genetically determined disease, 2) giving explanations about the mechanisms of transmission of genetically determined diseases, procedures and algorithm of genetic research, and 3) counseling on treatment and prevention, the further examination based on the results of genetic testing and genomic research [15]. Within the European community, there is a professional association of genetic counselors (European Network of Genetic Nurses and Counselors) that has approved its own ethical requirements and professional quality standards. By 2020 the EU plans to introduce uniform educational standards for training masters in the area of genetic counseling [16]. Outside the European community, the attitude towards determining the legal status of a person providing counseling services in the area of genetics remains ambiguous – the relevant profession either remains unrecognized neither by the state, nor by professional communities

(China, Russia, India), or it is regulated by the state through the establishment of professional standards that are obligatory for compliance (Cuba, Israel), or recognized by the professional community of geneticists that independently establishes the requirements for training a specialist, as well as ethical requirements for its activities (USA, Saudi Arabia, Australia) [17]. Thus, it is still relevant to solve the issue on the possibility of state recognition of the profession of a genetic counselor, as well as the degree of state participation in such activities through legal regulation.

Based on the comparative analysis of the state legal regulation of the cases when the disclosure of genetic information against the patient's will is allowed in order to protect the interests of third parties, it is possible to conclude that the exemption from the confidentiality principle is allowed taking into account such factors as the seriousness of the detected disease or genetic disorder, the availability of efficient treatment or preventive measures in relation to the pathology under consideration, and a confirmed degree of the diagnosis reliability [6].

There is an important aspect that requires a balance of state regulation and self-regulation of genetic research. It is related to national standards for services on genetic research [18]. The impact of professional associations, self-regulatory organizations of geneticists on the development of such standards depends on the general approach to the organization and determination of the legal status of such professional associations, as a whole. The world practice allows specifying two main approaches. According to the first one, professional associations are based on compulsory membership of specialists in the area of genetic research and are actively involved in the regulation of their activities. According to the second one, professional associations operate as voluntarily formed public organizations that mainly pursue the goal of promoting the development of genetic science and genomics, and protecting the rights and legal interests of their members. Such professional associations can participate in the regulation of the activities of specialists in the area of genetics only indirectly, through their participation in the development of professional standards, subsequently approved by states.

The first approach is reasoned by its focus on the specifics of genetic research. The need to take into account the opinion of the professional community in the matters that are regulated by the general provisions of the medical legislation does not provide the necessary quality control over the medical services provided, and the degree of protection of the citizens' rights and legal interests [19-20]. The followers of the second approach mainly pay attention to the need to maintain a unified approach to the development and implementation of educational standards in the states that regulate legal relations in higher and secondary vocational education [5]. Along with this, it is obvious that the ethical requirements in the area of genetic research must take into account interests of the professional community. At the same time, the binding nature of such requirements can be guaranteed only by such professional community that is based on the compulsory membership principle.

## V. CONCLUSION

The model of the optimal correlation of state regulation and self-regulation of legal relations related to genetic research can be formed based on the following principles:

1. Informed consent to genetic research and protection of the confidentiality of the information obtained from its results. The legal mode for the protection of the information obtained during the genetic research should be determined depending on classifying such research as a specific category – diagnostic (aimed at determining a certain genetic diagnosis), pre-symptomatic (aimed at identifying or

excluding mutations associated with a genetically determined disease a healthy person may get), or prognostic (aimed at assessing the individual's susceptibility to a certain disease). Third parties can only access the results of diagnostic genetic research. At the same time it is recommended to strictly define the cases when it is allowed to limit the principle of confidentiality of genetic information in the law (i.e., not at the level of the professional association of geneticists), including the provision of the genetic research results: 1) for processing and statistical generalization in the system of health care (if possible in a depersonalized form), 2) to persons belonging to the same related line for the diagnosis and treatment of genetically determined diseases and pathologies, 3) for the course of justice in criminal, civil, administrative proceedings (subject to the compliance with the set procedural guarantees), and 4) at the request of the data subject — to any private entity (to conclude an insurance agreement, an employer's health assessment, etc.). In the latter case, it is prohibited to obligate the provision of the genetic research results as a condition for providing any services, occurrence, amendments, or termination of labor and other legal relations.

2. Participation of self-regulated associations of medical geneticists in the development of national standards for the quality of medical services in the area of genetic research, as well as the requirements for medical organizations and medical employees who provide them (including the requirements of professional ethics – ethical codes).

3. Legalization of the legal status of the individual who provides counseling services in the area of genetic research and associated areas related to defining a strategy for treating genetically determined diseases and the use of assisted reproductive technologies (genetic counselors).

## ACKNOWLEDGMENT

The study was financially supported by the Russian Foundation for Fundamental Research (RFFR) within research project No. 18-29-14058.

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