

II. CONSTITUTIONAL AND ADMINISTRATIVE LAW

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CONSTITUTIONAL STATUS OF CITIZENS IN THE CONTEXT OF GENOMIC MEDICINE

G. B. Romanovskii

Penza State University
40, Krasnaya st., Penza, 440026, Russia

ORCID: 0000-0003-0546-2557

ResearcherID: S-7012-2016

e-mail: vlad1993gb@gmail.com

Introduction: the article considers the impact of genetic research on the constitutional status of the person and citizen and the changes in their legal personality. **Purpose:** to analyze the legislation defining the relations in the sphere of genomic medicine, genetic engineering; to identify problems emerging as a result of recent achievements in this field and predetermining a new attitude to the concept of human in law, their rights and obligations, and their place in the system of constitutional values. **Methods:** the methodological framework of this research is based on the analysis of statutory regulation, technical, and comparative law methods. **Results:** there is a common practice to define a subject of constitutional rights and liberties using indefinite pronouns, which allows one to refer to this category not only humans but also objects of genetic manipulations (clones, chimeras). As a result, there appear initiatives to extend constitutional rights and liberties to animals as well. Such lawsuits have many times been considered by the Supreme Court of the USA. **Conclusions:** it is shown that the development of genomic medicine is not taken into consideration in constitutional acts of most countries of the world. However, genetic engineering has now reached the level when its results can significantly impact on the human nature, changing it, among other things, by introducing animal DNA. Such experiments raise a question about assigning a special status to the human genome and proteome. It is necessary to protect the human nature from blurring of interspecies distinctions, from creating chimeras with *Homo sapiens* DNA. Recommendations are given to improve the legislation in the field of genomic medicine.

Keywords: human rights; constitutional status; genomic medicine; biomedical technologies; chimera

Information in Russian

КОНСТИТУЦИОННАЯ ПРАВОСУБЪЕКТНОСТЬ ГРАЖДАН В УСЛОВИЯХ ГЕНОМНОЙ МЕДИЦИНЫ

Г. Б. Романовский

Доктор юридических наук, профессор, зав. кафедрой уголовного права
Пензенский государственный университет
440026, Россия, г. Пенза, ул. Красная, 40

ORCID: 0000-0003-0546-2557

ResearcherID: S-7012-2016

e-mail: vlad1993gb@gmail.com

Введение: статья посвящена анализу влияния генетических исследований на конституционный статус человека и гражданина и изменений его конституционной правосубъектности. **Цель:** проанализировать законодательство, определяющее отношения в области геномной медицины, генно-инженерной деятельности. Выделить проблемы, возникающие в результате последних достижений в указанной области, которые определяют новое отношение к понятию человека в праве, его правам и обязанностям, их месту в системе конституционных ценностей. **Методы:** основу данного исследования составили такие методы исследования, как метод анализа нормативно-правового регулирования, формально-юридический и сравнительно-правовой методы. **Результаты:** установлена распространенная практика характеристики субъекта конституционных прав и свобод через неопределенные местоимения, что позволяет относить к нему не только человека, но и объекты генетических манипуляций (клон, химера). Продолжением данной логики является распространение конституционных прав и свобод на животных. Это подтверждается судебной практикой некоторых стран. Подобные судебные иски неоднократно рассматривались Верховным судом США. **Выводы:** показано, что развитие геномной медицины не учитывается конституционными актами большинства стран мира. Однако генно-инженерная деятельность достигла такого уровня, когда ее результаты могут активно влиять на природу человека, изменяя ее, в том числе, с помощью внедрения ДНК животных. Доказано, что подобные эксперименты обуславливают закрепление особого статуса генома и протеома человека. Сформулирован вывод о необходимости защиты человеческой природы от размывания межвидовых различий, от создания химер с набором ДНК *Homo sapiens*. Предлагаются рекомендации по совершенствованию законодательства в области геномной медицины.

Ключевые слова: права человека; конституционный статус; геномная медицина; биомедицинские технологии; химера

Introduction

The category “legal personality” holds a firm place in the theory of constitutional law. With respect to the human, it allows us to determine their place in the system of subjects of constitutional legal relations, to provide them with the corresponding scope of rights and obligations. Despite some theoretical developments, legislative acts hardly ever use this very term. It is absent from the Russian Federation Constitution as well.

At the same time, international legislation, starting from the Universal Declaration of Human Rights of December 10, 1948, not only contains ideas of this category but also provides the legal right of every human to recognition of their legal personality. There are similar provisions in the International Covenant on Civil and Political Rights of December 16, 1966 (Article 16), the American Convention on Human Rights of November 22, 1969 (Article 3), the African Charter on Human and People’s Rights of

June 26, 1981 (Article 5), the Arab Charter on Human Rights of 2004 (Article 1).

However, the absence of the right to legal personality in legislation does not mean the denial to recognize the human potential to enter constitutional relations, to possess constitutional rights and liberties. The Russian doctrine originally emanated from the idea that this kind of right belongs to each person and does not require any additional regulatory support. N. N. Alekseev defended the concept “absolute capacity to act”, which does not need any artificial legal determination [1, p. 80]. E. N. Trubetskoy considered recognition of human as a subject of law as the fact that “goes without saying” [6, p. 131]. I. A. Ilyin pointed at the essence of law, which is regulation of relations between people, on its assumption each person is a subject of law [2, p. 132].

Nowadays, genomic medicine is actively developing, which is changing ideas about the nature,

life and health of the human, and is also influencing legal elements of their status. Let us give an illustrative example. In Britain, after Daniel Martin's article "150 human animal hybrids grown in UK labs: Embryos have been produced secretly for the past three years"¹ was published in the famous tabloid "The Daily Mail" on July, 22nd, 2011, a scandal erupted. It turned out that during three years in the labs of three educational institutions experiments had been carried out to cross human and animal embryos. As a result, chimeras were created – embryos which contained mixed DNA. Considering the possibility (potential) of coming-into-being of both a human with animal genes and an animal with human genes, the question arises if the chimera will be considered a human in the constitutional meaning?

Constitutional Acts on Legal Personality

Article 17 of the Russian Constitution is the example of indirect assignment of citizens' legal personality. It uses a formula according to which rights and liberties belong to human from their birth. A similar statement model is characteristic of most European constitutions. For example, Article 32 of the Constitution of Malta starts with the words: "Whereas every person in Malta is entitled to the fundamental rights and freedoms..." Then there goes assignment of rights and liberties. Article 12 of the Constitution of the Republic of Kazakhstan provides: "Rights and liberties belong to every one from birth, are recognized as absolute and inalienable, determine the content and application of laws and other regulatory legal acts". There is a recital in Article 2 of the Italian Constitution: "The Constitution recognizes and guarantees inalienable human rights".

Article 10 of the Constitution of Spain states: "The dignity of the person, the inviolable rights which are inherent, the free development of the personality, the respect for the law and for the rights of others are the foundation of political order and social peace". Article 12 of the Turkish Constitution also points at possession of rights and liberties.

Direct assignment of legal capacity is a rare formula for constitutions of European countries. The exceptions are the Charter of Fundamental

Rights and Basic Freedoms of the Czech Republic (Article 5), the Constitution of the Slovak Republic (Article 14), the Fundamental Law of Hungary (§ 56).

European constitutions are also marked by the absence of specifying that human is the only holder of rights and liberties. The state is established by human and for human, that is why the absence of emphasizing human as the only subject of fundamental rights and liberties is taken for granted. On this assumption, the constitutions often use the negative pronoun "no one" or the defining pronoun "every".

For example, Article 7 of the Constitution of the Republic of Cyprus states: "No one can be deprived of life". A similar model is present in the Constitution of Belgium. The word combination "every one has the right" is common for national and international legislation. In the same way, the words "everybody" and "all" are used ("Everybody has the right to...", which is characteristic of the Constitution of Italy, or "All citizens" – typical for the Austrian Constitution). Article 6 of the Constitution of Belgium states: "All people are born free and equal in their dignity and rights".

Characteristic of the holder of rights and liberties by means of indefinite pronouns allows us to point out that not only a human can be the holder but also a chimera. According to such logic, constitutional rights and liberties should be extended to animals, too. In the USA, considering genomic characteristics of some animals that are not significantly different from human, they require constitutional rights and liberties for those animals. An active campaigner for this is Steven Wise (Professor of Law, teaches at Harvard), President of Nonhuman Rights Project². From this perspective, the Constitution of the Republic of Lithuania has a more distinctive character: Chapter II, which is devoted to relations between a person and state, all constitutional rights begin with the wording "A person has the right...".

Development of genomic medicine is not taken into consideration by constitutional acts. An exception is the Federal Constitution of the Swiss Confederation, which has two articles concerning the issue – 119 and 120. The former is aimed at protecting human from abuses of reproductive

¹ Martin D. 150 human animal hybrids grown in UK labs: Embryos have been produced secretly for the past three years. Available at: <http://www.dailymail.co.uk/sciencetech/article-2017818/Embryos-involving-genes-animals-mixed-humans-produced-secretively-past-years.html> (accessed 19.02.2017).

² Nonhuman Rights Project. Available at: <http://www.nonhumanrightsproject.org/> (accessed 20.02.2017).

medicine and genetic engineering. The latter protects human from abuses of genetic engineering in relations with the environment.

**Constitutional Legal Personality
of Animals Based on Their DNA:
Judicial Practice of Other Countries**

The abovementioned organization “Nonhuman Rights Project” is trying to stand up for constitutional rights of animals in the US judicial instances, referring to their genome. One of the first lawsuits was that in defense of a chimpanzee called Tommy that was private property and was kept in a cage by his hosts. The organization’s lawyers considered that the USA legislation has a general term “person” which can be used referring to the chimpanzee. The main argument was the chimpanzee’s DNA being 98 % identical to the human DNA. On that ground, the pleaders demanded to apply to Tommy all the guarantees provided in “*habeas corpus*”, consequently, to set him free from illegal confinement.

On December 4, 2014, New-York Court of Appeal made its final decision¹. The decision specially emphasized that using the term “person”, the rules of “*habeas corpus*” do not mention the human as the holder of rights and guarantees. However, the court added that in this part the law should not give definition to the concept “humans”, presupposing that they (only they) hold rights and liberties. History knows no case of extending rules of “*habeas corpus*” to animals. The Court of Appeal even made the study into understanding the essence of the human status. Existence of rights is conditional upon social duties and responsibilities: “Reciprocity between rights and responsibilities stems from principles of social contract, which inspired the ideals of freedom and democracy at the core of our system of government”. The Court also commented on the concept “person”, which can be natural (human) and legal. In any case, possession of rights is substantiated by the fact that the person can perform legal duties. Unlike a human, a chimpanzee cannot perform any duties and have responsibilities, consequently, it cannot have rights. The decision has a supplement: “The law establishes other forms of animal protection”.

¹ Appellate Division. Third Judicial Department / Available at: <http://decisions.courts.state.ny.us/ad3/Decisions/2014/518336.pdf> (accessed 20.02.2017)

It should be noted that “Nonhuman Rights Project” did not give up at that. They collected various proofs that cognitive (intellectual) functions of apes are developed almost like those of humans. Similar arguments were often used by Justin Marceau (Professor of constitutional and legal law, University of Denver) and Samuel R. Wiseman (Professor of constitutional and legal law)², Lawrence Tribe (Professor of constitutional law, Harvard University)³.

Two more pleas were made to defend chimpanzees Hercules and Leo, who had been subject to experiments at the University of Louisiana. However, in July 2015 the claimants were adjudicated. The court decision stated: “Chimpanzees are not given any legal rights except protection from cruel treatment and abuse”. Thus, the Court of Appeal dismissed the plea in this case, too. In autumn 2016, they submitted a plea in defense of the chimpanzee Kiko, but it was also dismissed by the judicial instance. However, the lawsuit continues, new hearings of the case are appointed for spring 2017.

In 2008 Austrian animal rights activists made a plea in which they demanded to declare chimpanzee Matthew to be the holder of rights. The decision was negative. A complaint was made to European Court of Human Rights, which was considered unacceptable despite the active social campaign in its support⁴.

In December 2014, the Argentinian court resolved that the orangutan called Sandra should be considered the same holder of rights as a human. The 28-year-old ape was kept in Buenos-Aires zoo until animal rights activists made the corresponding claims to treat her as a human in philosophical, not biological sense⁵. The court decision referred to the work by Raul Zaffaroni “Criminal Law. General Part” [27], where he appeals to legislators to change their attitude to animals as if they were things.

² Nonhuman Rights Project. Available at: http://www.nonhumanrightsproject.org/wp-content/uploads/2016/12/2016_15_0149_Tribe_ITMO-The-NonHuman-Right-Project-v.-Presti_Amicus-1-2.pdf (accessed 21.02.2017).

³ Ibid.

⁴ Hall. A. European Court agrees to hear chimp's plea for human rights. Available at: <http://www.dailymail.co.uk/news/article-1020986/European-Court-agrees-hear-chimps-plea-human-rights.html> (accessed 21.02.2017).

⁵ Court in Argentina grants basic rights to orangutan. Available at: <http://www.bbc.com/news/world-latin-america-30571577> (accessed 21.02.2017).

Genomic Medicine and the Human Legal Status

Development of genomic medicine is connected with two tendencies which have a direct relation to the legal status of a human: genetic diagnosis and genetic therapy.

Genetic diagnosis, in its turn, is connected with genetic testing (it is impossible to identify the human DNA without testing the person), which is testing a person to find out some features of their genetic system. In our country, there is Federal Law of December 3, 2008, No. 242-FZ “On State Genomic Registration in the Russian Federation”¹. However, its subject matter is limited by a range of relations which it refers to: only those ones which relate to compulsory and voluntary genomic registration aimed at identity verification (Article 1). It is noteworthy that national acts of most countries determine exactly such narrow usage of the information received from DNA. As an example we can mention Federal Republic of Germany Law of July 31, 2009 on genetic testing (GenDG)², which entered into force from February 1, 2010, as well as Law of France of August 6, 2004, No. 2004-800 “On Bioethics”³, devoted, among other things, to regulating relations in genetic diagnosis.

Article 15 of the RF Family Code expands the limits of genetic diagnosis a little by providing an opportunity for medical examination of people who are going to get married, which includes consultations on medical and genetic issues. In this case, information about one’s DNA and one’s partner’s DNA will go beyond the limits of general informativity. It will result in forecasting the future children’s DNA. Russian legal science has many times offered to make genetic testing compulsory [3, p. 16; 5, p. 25; 7, p. 14]. In the USA, medical workers become subjects against whom pleas are made by close relatives because the doctors kept the information about genetic predisposition to some diseases secret. In spite of this, the general

opinion is that medical information must not be disclosed [23]. In the USA, employers pay for secret genetic testing during medical check-ups of their employees who demand compensations when they develop professional diseases. Medical staff disapprove of such tests; their usage leads to data exception from evidentiary base when the case is heard in court [18]. In any case, a medical worker should abide by the therapeutic contact with the patients and their families [12]. Italian practice allows for disclosure of certain aspects of genetic information to the patient’s close relatives even when there is no patient’s consent to such disclosure [11]. However, most ethical difficulties emerge when disclosing genetic information to children. Medical staff introduce the term “DNA information management” evaluating the risk of providing this information to the under-aged [15].

The consequences of this narrow interpretation of genetic testing results leads to propaganda of discriminating “handicapped” citizens. For example, D. T. Lykken (psychologist, eugenicist) defended his point of view on establishing regulatory procedures of giving birth. The main point was that human behavior always depends on their genetic data [21].

It is suggested that achievements of genomic medicine be used for criminological purposes. C. Lombroso [4], M. Dugdale [13], H. Goddard [16] and some others were engaged in looking for “born criminals”. In 1965, Patricia Jacobs made a sensational announcement that it is male chromosomal abnormality of XYY type that causes criminal behavior. Based on her conclusion, it was decided in the USA to test all men to find out the presence of the extra chromosome, to introduce specialized police record keeping.

It was later proved that P. Jacobs’ research was superficial and her announcement was intended to be a sensation. However, it does not stop the efforts of medics and criminologists. For example, the USA researchers link aggressive behavior to the gene responsible for serotonin production [26]. Finnish researchers revealed the connection of criminal behavior with a set of certain genes [24].

Genetic consultation can be provided for adult population as well as for the under-aged. It can be applied to the unborn. Pre-implantation genetic diagnosis is being actively introduced; it is used

¹ Collection of Legislative Acts of the Russian Federation. 2008. No. 49. Article 5740.

² Positionspapier zum Gendiagnostikgesetz-Entwurf sowie zur Umsetzung des Gendiagnostikgesetzes. Available at: http://www.biodeutschland.org/tl_files/content/positionspapiere/BIO_D_Position-Diagnostikgesetz.pdf (accessed 21.02.2017).

³ Loi No. 2011-814 du 7 juillet 2011 relative à la bioéthique. Available at: <https://www.legifrance.gouv.fr/affichTexte.do?dateTexte=&categorieLien=id&cidTexte=JORFTEXT000024323102&fastPos=2&fastReqId=1995621777&oldAction=rechExpTexteJorf> (accessed 21.02.2017).

under reproductive technologies connected with artificial placement of an embryo into a woman's womb.

Carrying out mass screening of adult population, creating genetic IDs of each citizen will cause different abuses. The practice already shows that those most interested in getting genetic information are credit and insurance organizations, employers. Banks might want to establish an additional insurance mechanism when giving long-term credits to those citizens who show disposition to certain diseases. Insurance companies are already making their complaints as barriers to possible abuses from the citizens who have interest in getting insurance as they know what kind of disease they may develop in their future life [19].

Employers can establish barriers when recruiting, refusing applicants who might have disposition to certain professional diseases. It is a possible way of protection from a claim made by the employee who has already developed such a disease caused not by work conditions but by their genotype.

Genetic testing of the under aged (let alone embryos) is connected with getting an informed consent as well as with the "right to an open future" (the expression is used in the western doctrine [14]). Will an adult be happy with the disclosure of their genomic information if he cannot keep it secret anymore? His parents have already given orders on the DNA disclosure. Moreover, prenatal genetic testing leads, as a rule, to recommendations about termination of pregnancy and induced abortion. Nowadays, in force is Decree of the Ministry of Health of the Russian Federation of December 28, 2000, No. 457 "On Advancing Prenatal Diagnosis in Preventing Hereditary and Congenital Diseases in Children". This document states: "Under certain indications there are recommendations to terminate pregnancy". Such provisions have ambiguous ethical assessment. All the more so because abuses of prenatal diagnosis end up with autotegenics – selection on the basis of sex. In some parts of the world, there are still deep superstitions about female inferiority. History witnessed such middle-aged works as "Woman is not human" (Frankfurt, 1690), "A curious evidence that a wom-

an does not belong to mankind" (Leipzig, 1753) [9, p. 875]. However, even now some peoples consider it a natural mistake if a girl is born.

Genetic therapy is a complex of genetic engineering (biotechnological) and medical methods aimed at introducing changes into genetic apparatus of somatic cells of a human in order to treat diseases. Such definition is presented in Article 2 of the Federal Law of July 5, 1996, No. 86-FZ "On State Regulation in the Sphere of Genetic Engineering"¹. Until recently, genetic therapy was considered as the possibility of preventing hereditary diseases. However, genomic medicine offers new kinds of treatment with the use of the altered genotype of cells, delivered right to the place of processing (for example, when treating cancer diseases – to the place of the tumor localization).

On January 1, 2017, Federal Law of June 23, 2016, No. 180-FZ "On Biomedical Cell Products"² came into effect. It is hoped to promote biomedical technologies, including those connected with achievements in the sphere of genetics.

The main difficulties concerning genetic therapy are linked to determining the very medical technology which is not under the general regime of regulating medical intervention. A medical worker performing actions is experimenting. He cannot anticipate to the full the consequences of treatment with biomedical cell products. Additional difficulties arise when gene therapy is applied to the unborn (*in utero*). Federal Law of November 21, 2011, No. 323-FZ "On Principles of Healthcare of the Russian Federation Citizens"³, enshrining the model of the informed consent to any medical intervention, does not provide any exceptions. Although in the case under consideration, the parents' consent in relation to the one who has not been born yet is beyond the standard scheme. It is worth mentioning that judicial practice has seen some claims from disabled children against doctors and parents who refused to follow the recommendations

¹ Collection of Legislative Acts of the Russian Federation. 1996. No. 28. Article 3348.

² Ibid. 2016. No. 26 (Part I). Article 3849.

³ Ibid. 2011. No. 48. Article 6724.

to terminate pregnancy [17]. There is now even a term “illegal keeping alive” [20].

The modern achievements of gene therapy establish the ground for eugenics, thus predetermining serious questions: Is compulsory gene therapy permissible? Is compulsory gene therapy permissible for the unborn (in utero)? Is it allowed to create a human with traits programmed in advance? These are far not all the questions.

Modern Political and Legal Doctrines on Genomic Medicine

Achievements in genomic medicine raise a serious question about the place of a human in the system of constitutional values. Technological attitude has a serious ideology under it. Alexander Bard and Yan Soderquist created a holistic view of the world and gave it a new term – netocracy [10], which should be based on exceptional pragmatism. Genetics is given a special place. It is supposed to perform social functions, to substitute the law of natural selection: “Given the knowledge on their genetic background, for the first time in their history people will be able to plan their lives on the assumption of their basic information. They will be able to choose the most suitable careers and education, to plan to have children with the partner who has the most suitable set of genes, to decide not to eat unhealthy food, etc. Authorities and employers will have access to tools of perfect testing of workers and employees”.

This approach leads to control over birthrate. The authors offer to put births under strict laboratory control. The ideal is non-natural generation. By the way, some countries conduct active research into creation of an artificial womb to prevent a woman from bearing a child. Such research is being carried out at the University of Tokyo, Cornell University and Illinois State University [22]. In case of success, the consequences may be of a global character: 1) new vision of the problem of abortions (the fetus can be artificially carried to full time); 2) changes in gender ideas about a woman (loss of monopoly on reproductive performance); 3) having children will turn into a technological process; 4) access of homosexual couples to this technology; 5) legalization of reproductive cloning.

Manipulations with human genes were positively evaluated by Alvin Toffler, who viewed it as the creation of a human new “version”

[25, pp. 219–220]. His idea is to transfer to the technological method of having children when geneticists work out the characteristics of a future child. “A child with a guaranty that he is free from genetic faults” is the future world ideal in Toffler’s view. Birthing centers will more look like supermarkets where you can discuss all the features of future children: the color of their eyes, skin, their IQ, etc. Alvin Toffler demonstrates the perspectives of extrauterine births, which should help in possible colonization of other planets.

Francis Fukuyama, a famous futurologist, also points out that development of biomedical technologies will influence almost all social institutions: “It will shake up all the existing social hierarchies and influence the rate of material, intellectual and political development, and it will change the nature of global policy” [8, p. 122]. The scholar emphasizes that the logical continuation of gene industry will be not only the knowledge about human DNA but also the desire to improve “basic data”. Due to the fact that an adult person will not be able to correct their nature, their wishes will be transferred onto their children. “The main prize of modern genetic technology will be “a baby on a by-order basis”, F. Fukuyama draws his conclusion. At the same time, the philosopher reminds that genetics “has long been haunted by eugenics – conscious development of certain qualities in people with the help of selection”. Will people be able to resist the temptation to change their own nature, though on the assumption of speculative preferences? The work provides a demonstrative comparison. Changes in human genome for eugenic purposes will be similar to having a fashionable tattoo, however, it will be impossible to get rid of it not only for those who have it but also for all next generations. F. Fukuyama describes one more fear: what if human DNA will be mixed with other species DNA and clarity of understanding a human will disappear? Speaking about this, F. Fukuyama comments on the lack of sufficient regulatory acts that might provide guarantees in cases of possible abuses in genetics.

International Law on the Human Genome

Achievements in the field of genomic medicine are of universal character. That is why international community expresses general concern and is trying to work out unified rules which might

become a certain landmark for national legislators. On November 11, 1997, the Universal Declaration on the Human Genome and Human Rights¹ was adopted. The document establishes the general principles:

1) The human genome is heritage of mankind.

2) Each person has the right to respect of their dignity and rights independent of their genetic characteristics. Any discrimination based on genetic features is prohibited.

3) Due to evolution, the human genome is subject to mutation.

4) The human genome in its natural condition must not be the source of making profit.

The Declaration also contains certain guarantees aimed at protecting people from possible abuses in the sphere of genetics:

– Evaluation of potential dangers under any genetic research is given.

– The obligatory condition for conducting research is getting an informed voluntary and prior consent from the interested person.

– Each person decides for themselves if they need information about the results of genetic diagnosis.

– The state should provide privacy of the information received about citizens' DNA.

– Human cloning is prohibited.

– Freedom of research is guaranteed but is should not prevail over respect of human rights and liberties.

On October 16, 2003, the UN International Declaration on Human Genetic Data² was adopted, which specified the importance of genetic data. It was also caused by the fact that by that time the program of human DNA decoding had been implemented. Science received the basic information which originates from genetic features of each person. In view of this, the document did not declare general principles of conducting research (which can be applied to any sphere of science) but pointed out particular requirements to genetic diagnosis and gene therapy. It is especially emphasized that goals

of collecting genomic and proteomic human data go far beyond personality identification. They include prognostic testing, population research, creating personalized methods of treatment, etc. The Declaration of 2003 points at the need of special confidentiality regime in relation to genetic data as it can influence not only the life of a particular person but also that of his descendants, or population as a whole.

A little later, in October 2005, Universal Declaration on Bioethics and Human Rights³ was adopted by acclamation. On March 8, 2005, the UN Declaration on Human Cloning⁴ was ratified, which prohibits reproductive human cloning (creating a human specimen).

Among regional documents, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is worth mentioning (Convention on Human Rights and Biomedicine, Oviedo, 1997). Chapter IV of this document, called "The human genome", partly repeats the key provisions of the Declaration on the Human Genome. It emphasizes that genetic testing can be carried out only for medical purposes. Autoeugenics is prohibited. It is banned to create a mutated organism. Intervention into the human genome should not lead to altering the genome of this person's descendants. However, despite being very significant, the effect of this international document is limited by the area of Europe. Article 34 provides for an opportunity for other non-European countries to accede to it. However, not all the Council of Europe countries are its members, including Russia.

In 2005 a Supplementary Protocol to the Convention was adopted concerning the sphere of biomedical research (SDSE No. 195). It came into effect on September 1, 2007. The Protocol regulates specific areas of biomedicine but has indirect relation to genetic research. In November 2008, a Supplementary Protocol to the Convention on Human Rights and Biomedicine was elaborated, referring to genetic testing for medical purposes

¹ Universal Declaration on the Human Genome and Human Rights. Available at: http://www.un.org/ru/documents/decl_conv/declarations/human_genome.shtml (accessed 19.02.2017).

² UN International Declaration on Human Genetic Data. Available at: http://www.un.org/ru/documents/decl_conv/declarations/genome_dec.shtml (accessed 19.02.2017).

³ Universal Declaration on Bioethics and Human Rights. Available at: http://www.un.org/ru/documents/decl_conv/declarations/bioethics_and_hr.shtml (accessed 19.02.2017).

⁴ UN Declaration on Human Cloning. Available at: http://www.un.org/russian/document/declarat/decl_clon.pdf (accessed 19.02.2017).

(SDSE No.203). By now, it has been ratified by four countries being the Council of Europe members but it has not come into effect yet.

Russian Legislation Defining the Legal Status of Genomic Medicine

In the Russian Federation, medical activity is regulated by Federal Law of November 21, 2011, No. 323-FZ “On the Principles of Health Protection of Citizens in the Russian Federation”¹. The document regulates the rights and duties of patients and medical workers in all issues of their professional activity. However, specific features of genomic medicine are not reflected in the legislation. The only time when medical genetic consultations (and nothing more) are mentioned is in Article 51 of this law, devoted to providing consultations on certain aspects of family and marital relationships. Similar provisions are contained in the RF Family Code (Article 15), according to which there is voluntary medical genetic consulting of people about to get married.

The above mentioned Federal Law of July 5, 1996, No. 86-FZ “On State Regulation in the Sphere of Genetic Engineering” has a direct relation to genomic medicine. However, as a detailed analysis of its provisions shows, regulation of activity in relation to the human body is regarded as a side effect. Firstly, before the year 2000 the law directly stated that it did not cover those relations that emerge on the issue of applying genetic engineering methods to human, tissues and cells of the human body. Secondly, changes concerning subjectology were of a narrow character. Concerning non-application of the law to genetic engineering in relation to the human, a supplement was developed – “except genetic diagnosis and gene therapy”². However, the rest of the law remained unchanged. Thirdly, the recent amendments to Law No. 86-FZ, introduced by Federal Law of July 3, 2016, No. 358-FZ, despite containing references to human healthcare, deal only with GMO products dis-

tribution. Fourthly, Federal Law “On State Regulation in the sphere of Genetic Engineering” itself presents a kind of a technological instruction, determining requirements to people engaged in genetic engineering, enumerating activities in the sphere of genetic engineering, establishing the safety system in the sphere of genetic engineering activity, etc. At the same time, there are no regulations in the law devoted to protecting the rights of a person as an object of genetic engineering, as a patient.

Federal Law of December 3, 2008, No. 242-FZ “On State Genomic Registration in the Russian Federation”³ has an indirect relation to genomic medicine, but its regulation subject includes only the relations connected with compulsory and voluntary genomic registration for the purpose of personality identification. As soon as genomic medicine spreads considerably, there will be questions of using DNA for passportization, transferring data into electronic resources, and changing the whole technology of treating each person depending on their biological data. If an informational medical database containing DNA data about each person is established, it will be necessary either to introduce amendments into Federal Law “On State Genomic Registration in the Russian Federation” (which is more preferable) or to pass a new regulatory act. In any case, additional regulations shall identify the rules of collecting, processing, disseminating and using information on human genome and proteome. It will be obligatory to establish a strict system of information protection which will guarantee against unauthorized access and illegal copying. The law shall determine the cases of information systematization without the citizen’s consent. Otherwise, all discrimination forms known to history will fade away when faced with the stigmatization which might occur as a result of dividing citizens according to the principle of their genetic predisposition.

In the Russian Federation, human cloning is banned, which is stated in Federal Law of May 20, 2002, No. 54-FZ⁴. The specific feature of this

¹ Collection of Legislative Acts of the Russian Federation. 2011. No. 48. Article 6724.

² Federal Law No. 96-FZ “On Amendments and Additions to the Federal Law “On State Regulation in the Sphere of Genetic Engineering”” of July 12, 2000. *Collection of Legislative Acts of the Russian Federation*. 2000. No. 29. Article 3005.

³ *Ibid.* 2008. No. 49. Article 5740.

⁴ Federal Law No. 54-FZ “On the Temporary Ban on Human Cloning” of May 20, 2002. *Collection of Legislative Acts of the Russian Federation*. 2002. No. 21. Article 1917.

regulatory act is that it imposes only a temporary ban but does not determine the duration of this ban. The ban is substantiated by the following: “biological and social consequences of human cloning are not studied well enough”. Obviously, it is supposed that the ban might be lifted when the corresponding biomedical technologies develop. However, special research into human cloning in the Russian Federation is not under way.

Conclusions

Genomic medicine is developing rapidly, having achieved the level when its results can directly influence the human nature by changing it, among other things, with the help of introducing animal DNA into it. Experiments of this kind, carried out in different countries on a regular basis, raise serious issues on introducing a special status of the human genome and proteome. The human nature must be protected so that advances in biotechnologies would not lead to blurring of interspecies distinctions, would not contribute to creating chimeras with *Homo sapiens* DNA set.

Up to now, constitutional acts when defining each citizen as a subject of law have not used the wordings which would unambiguously point at a human as the only holder of rights and duties. Impersonal expressions are nowadays used in an effort to apply constitutional protection to animals. Such practice is based on the insignificant difference between the human DNA and DNA of some animals (foreign practice most usually refers to human-like apes). Despite the fact that these lawsuits are rather exotic ones (they are initiated in the USA and some other countries), ideological brainwashing in the world is gaining momentum.

Analysis of the Russian legislation concerning genetic technologies reveals that it does not keep up with the reality. Even a brief review shows that it is necessary to establish at least some minimal bans which exist all over the world: those concerning collecting, storing, processing and using information about the human DNA by non-medical organizations; genetic diagnosis and systematization of information by foreign organizations without the corresponding permission from the RF government; using genetic information for other non-medical purposes except as expressly provided for by law; creating chimeras; involving human embryos into

genetic experiments. It is necessary to introduce guarantees that the bans are enforced, in particular, by amending criminal legislation of the Russian Federation.

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