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Legal Aspects of the Protection and Limits of the Possible Human Genomeuse

Elena V. Luneva and Zavdat F. Safin

Abstract--- *Based on the analysis of the works of Russian and foreign lawyers specializing in the legal regulation of genomic research, as well as the work of geneticists and biochemists, the legal aspects of protection and the limits of the possible human genome use are considered. The problems concerning the declared topics in various branches of law and legislation are identified. It is shown that the use of information about the human genome, and manipulations with it allow us to fight crime, counter various types of human diseases, solve reproductive problems, and so on. Nevertheless, despite the wide range of positive aspects of human genomic technologies, the risks in the form of unpredictable consequences for subsequent generations from them are much more dangerous and greater, which affects the features of the human genome legal protection and the limits of its use. In legal science and in various branches of law, the need to strengthen legal prohibitions and restrictions regarding the modification and use of the human genome is recognized. In addition to the main prohibition on human cloning, additional prohibitions are introduced everywhere with specific measures of legal liability. The legal nature of the human genome remains uncertain. The variety of scientific discussions and disputes about the human genome characteristics in different branches of law and legislation do not solve yet the question of what kind of objects of rights it should be attributed to.*

Keywords--- *Legal Regulation, Human Genome, Cloning, Genomic Information of Patients.*

I. INTRODUCTION

According to Article 13 of the Convention for the Protection of Rights and Human Dignity in Connection with the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 04/04/1997, ETS No. 164) intervention in the human genome aimed at its modification can be carried out exclusively for preventive, diagnostic or therapeutic purposes and only on condition that it does not lead to a change in the genome of his/her heirs. This document confirms that scientific research on the modification of the human genome is very much in demand, but is related to numerous risks.

Coordination of diverse legal means is required for the effective legal regulation of the human genomeprotection and the determination ofthe possible limits of its use. Therefore, a systematic approach (the interaction between different branches of law and legislation) to the legal support of relations related to the human genome is advisable. ***The purpose of this work*** is to identify the specifics of legal protection and the limits of the possible use of the human genome.

Elena V. Luneva, Kazan Federal University, Kazan, Russian Federation. E-mail: vilisa_vilisa@mail.ru
Zavdat F. Safin, Kazan Federal University, Kazan, Russian Federation.

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II. MATERIALS AND METHODS

The legal aspects concerning protection and limits of the possible use of the human genome were studied on the basis of an analysis of the works which authors are Russian and foreign lawyers specializing in the legal regulation of relations that somehow affect the human genome (***I. Ajunwa, B.J. Evans, R. Hazin, S. Lavi, P. MacFarlane, L. Motta-Murguia, S. McSwiggan, J. Robienski, M.A. Rothstein, S.M. Wolf,*** et al.).In addition, the findings were based on the work of geneticists and biochemists (***O.E. Anikeev***, ***O.A. Kravtsova***, etc.).

The methodological basis of the study was the dialectical method, which made it possible to learn in indissoluble unity and in a general connection the features of social relations associated with the change or use of the human genome.The achievement of the goal set in the introduction was also promoted by logical methods in the form of analysis and synthesis, induction and deduction, comparison and generalization, analogy and typology. The formal legal technique helped to clarify the importance of diverse legal means aimed at protecting and limits the use of the human genome.

III. RESULTS

The scope of legal research on the human genome should be recognized as relatively developed in comparison with the legal regulation of relations on the change in the genomes of other living organisms. This situation is explained by the international action of the Universal Declaration on the human genome and Human Rights (12/11/1997), the Convention for the Protection of Human Rights and Human Dignity in Connection with the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, and others international documents.

In addition, the following regulatory legal acts have been adopted in Russia that affect the study of the human genome: Federal Law dated 03.12.2008 No. 242-FZ “On State Genomic Registration in the Russian Federation”, Decree of the President of the Russian Federation dated 28.11.2018 No.680 “On the Development of Genetic Technologies in the Russian Federation”, Decree of the Government of the Russian Federation No. 828 dated 11.10.2011 “On approval of the Regulation on the procedure for compulsory state genomic registration of persons convicted and serving sentences of imprisonment”, Government Order of the Russian Federation dated December 28, 2012 No. 2580-r “On approval of the Strategy for the development of medical science in the Russian Federation for the period until 2025” and other documents.

Consider the developments of Russian and foreign lawyers specializing in the legal regulation of relations relating to the human genome in certain branches of law and legislation.This approach will allow a comprehensive assessment of legal remediesand the limits of the possible use of the human genome.

IV. DISCUSSION

International law. An analysis of the international legal regulation of genetic research was carried out by G. B. Romanovsky. He concluded that recent advances in genetics necessitate the adoption of a universal convention on human rights and bioethics. The legal scholar has shown the feasibility of creating a supranational body that monitors the results of scientific achievements in the field of genetics, which would give advisory opinions [1].

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Foreign lawyers give a critical assessment of the growth of international governance in the field of genetics and reproductive technologies as “legal cloning”. They recognize the dangers of biotechnology and cloning techniques that will lead to a decrease in human diversity. Subsequently, a controlled uniformity of the human community may arise [2].

The following problems are recognized as the most urgent in ensuring the integrity of the human genome: the creation of an appropriate legal framework for the therapeutic cloning of individual cells in order to help terminally ill patients; prohibition of reproductive and other illegal cloning; determination of the permissibility limits for using genetic engineering data in the fight against crime [3].

Forensics. Genomic research plays a significant role in the practice of crime detection and investigation. So, with a high degree of certainty, the forensic biological examination of human DNA (genomic examination of DNA) allows solving identification problems in the fastest way [4]. Forensic identification is also carried out based on the achievements of genotypic identification [5].

Despite the arsenal of tools available to biochemists and geneticists, an investigative practice needs the development of instrumental methods of molecular genomic research [6]. Phenolchloroform extraction and the PrepFiler Forensic DNA Extraction Kit system are recognized as the most preferred methods of isolation from muscle and bone tissue, as well as objects containing cadaveric blood to obtain high-quality DNA. The Qiagen DNA Mini Kit and DNA IQ System [7] are recommended for DNA extraction from hair, sweat and grease prints, including after treatment with dactiloscopic powder.

In criminal proceedings, the results of behavioural genomics are used. It has been proven that a low activity monoamine oxidase enzyme (MAOA-L) genotype can increase the risk of aggressive and antisocial behaviour.As a result of a study of court documents related to the MAOA-L genotype, using the legal databases of Westlaw and LexisNexis between 1995 and 2016, it was found that evidence of the MAOA-L genotype was included in the records of 11 criminal cases [8].

If the improvement of diagnostic methods using genomic analysis in forensics is clearly perceived as progress and a positive phenomenon [9, 10], then the patients’ genomic information, and especially its availability for various applications in medicine, raises many questions [11-15].

Medical law. D.K. Rashidkhanova devoted her work to the problems of regulation of medical interventions for cloning the human genome. Based on the growth in the number of various forms in which infertility among couples is manifested, she suggested that the products of the market for cloning services would be in demand quite widely, and legislative prohibitions of cloning would not be effectively implemented in practice. She formulated a number of additional legal prohibitions on the production of medical services for the reproduction of the human genome [16]. To comply with these prohibitions, it is proposed to establish criminal liability. This may be the offences related to the provision of proper protection of citizens during genetic manipulations, including the protection of embryos [17]. In addition to cloning, genomic studies that invade the legal principles of human status include regenerative medicine, gene therapy, experiments with embryonic stem cells, and the use of cord blood for medical purposes, etc. [18]

G.B. Romanovsky showed the level achieved by genetic engineering, when its results can actively affect the nature of man changing it, including through the introduction of animal DNA [19]. Such experiments determine the consolidation of the special legal status of the human genome and proteome. The conclusion is made about the need to protect human nature from blurring interspecific differences, from creating chimaeras with a set of Homo sapiens DNA. Foreign authors also write about a similar legal regulation of genetic testing within the framework of gene diagnostics [20].

In many states, the legal opportunity to transfer biological materials outside the country for the study of genetic populations is provided. Despite the fact that such permissions are the basis of the genomic sovereignty of a particular state, they do not impede international cooperation [21].

The key problem of legal regulation in the development of genetics and genetic engineering in medicine was determined by M.O. Kvachadze. He gave the main role to the limits of permissible interference of law, medicine and biology in the human being, so as not to affect human dignity and not violate fundamental human rights [22].The issue of the correlation between ethics, science and law [23] comes to the fore here. We believe that the legal regulation of research and the use of the human genome should be based on reasonable limits of interference with the human being. But how to define them? The task is complex and unresolved so far.

In the joint field of medical, labour and social security law, there are scientific developments related to the ban on the disclosure of the genomic and genetic information of a particular person. Foreign legal colleagues come to the conclusion that the ease of access to genetic testing and the lack of security of genetic information have increased the likelihood of genetic discrimination in employment. Real cases of genetic testing have shown that it can lead to racial disproportions [24]. An assumption has been made about the legal possibilities for retirement communities and older people's centres to use information about the genetic risk of humans regarding the occurrence of Alzheimer's disease [25].

Family law. The human genome is also partially affected by the legal regulation of assisted reproductive technologies. For example, A.P. Kokorin discusses the sufficiency of the fact concerning the genetic relationship of a child born by a surrogate mother to acquire parental rights. The genes of the child coincide with the genes of the spouses; however, the surrogate mother provides all the biological material from which the child’s body is formed (the nutrients that the body consumes for nine months). He asks the question: whose “contribution” in this case is more significant? [26].

Civil law. The human genome problems are also covered by civil law. In civil law, a unified approach to the human genome as an object of civil rights has not been developed (if at all it is reasonable to consider it that way).A.A. Pestrikova discusses the legal affiliation of the human genome, as well as the difficulties associated with determining the owner of the biomaterial and the entity entitled to receive income from the use of the biomaterial for commercial purposes [27,30].She believes that these relations cannot be strictly classified as property or personal non-property rights; the introduction of new legal categories and structures is required [28,31]. However, there are scientists who recognize the human genome as an intangible good from the standpoint of objects of civil rights [29,32,33].

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V. SUMMARY

In various branches of legal science, the need to strengthen legal prohibitions and restrictions regarding the modification and use of the human genome is recognized. In addition to the basic prohibition on human cloning, many states impose additional prohibitions, including prohibitions on reproductive cloning, on genetic manipulation of embryos, restrictions on the use of information on human genetic risks with specific legal liability measures.

The legal nature of the human genome remains uncertain. The variety of scientific discussions and disputes about the characteristics of the human genome in different branches of law and legislation do not solve the question about what kind of legal objects it should be attributed to.

VI. CONCLUSION

The use of information about the human genome, and manipulations with it, allow us to fight crime (forensic identification, etc.), provide resistance to various types of human diseases (regenerative medicine, gene therapy, etc.), and solve reproductive problems, and so on. Nevertheless, despite the wide range of positive aspects of human genomic technologies, the risks in the form of unpredictable consequences for subsequent generations from them are much more dangerous and great (up to a radical change in the appearance of a person and a decrease in genetic diversity to a critical level).

CONFLICT OF INTEREST

The authors confirm that the data presented do not contain a conflict of interest.

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REFERENCES

[1] Romanovsky, G.B. (2007). Genetic research and international law. *International public and private law*, 4, 10-14.

[2] Lavi, S. (2014). Cloning International Law: The Science and Science Fiction of Human Cloning and Stem-Cell Patenting. *Law culture and the humanities, 14*, 83-99.

[3] Evans, B.J. (2018). Commentary: HIPAA's Individual Right of Access to Genomic Data: Reconciling Safety and Civil Rights. *The American Journal of Human Genetics*, 102, 5-10.

[4] Latypov, S.I. (2015). Possibilities of using handprints for conducting a forensic biological examination of human DNA. Forensic expert, 4, 33-34.

[5] Drapezo, R.G., & Yurkevich, N.A. (2017). The problems of conducting pre-trial verification in murder cases, where the fire acts as a tool (method) for concealing a crime. *Russian investigator*, 20, 11-16.

[6] Romanov, V.I. (2015). Forensic technology and the needs of investigative practice. *Russian investigator*, 24, 13-16.

[7] Anikeev, O.E., Stepushenko, Yu.G., Gazetdinov, N.I., Kravtsova, O.A. (2013). Comparative characteristics of methods for DNA extraction from various objects of biological origin during genotypic examination. *Russian investigator*, 1, 2-4.

[8] McSwiggan, S., Elger, B., & Appelbaum, P.S. (2016). The forensic use of behavioural genetics in criminal proceedings: Case of the MAOA-L genotype. *International Journal of Law and Psychiatry*, *50*, 17-23.

[9] Shabani, M., Borry, P., Smeers, I., & Bekaert, B. (2018). Forensic Epigenetic Age Estimation and Beyond: Ethical and Legal Considerations. *Trends Genet.*, (18).

[10] Wasser, S.K., Brown, L., Mailand, C., Mondol, S., Clark, W., Laurie, C., & Weir, B.S. (2015). Genetic assignment of large seizures of elephant ivory reveals Africa's major poaching hotspots. *Science*, *349*(6243), 84-87.

[11] Borry, P., Bentzen, H.B., Budin-Ljøsne, I., Cornel, M.C., Howard, H.C., Feeney, O., & Riso, B. (2018). The challenges of the expanded availability of genomic information: an agenda-setting paper. *Journal of community genetics*, *9*(2), 103-116.

[12] Wolf, S.M. (2017). The continuing evolution of ethical standards for genomic sequencing in clinical care: restoring patient choice. *The Journal of Law, Medicine & Ethics*, *45*(3), 333-340.

[13] Wolf, S.M., Amendola, L.M., Berg, J.S., Chung, W.K., Clayton, E.W., Green, R.C., Harris-Wai, J., Henderson, G.E., Jarvik, G.P., Koenig, B.A., Lehmann, L.S., McGuire, A.L., O'Rourke, P., Somkin, C., Wilfond, B.S., & Burke, W. (2017). Navigating the Research-Clinical Interface in Genomic Medicine: Analysis from the CSER Consortium. *Genetics in Medicine*, 1-9.

[14] Hazin, R., Brothers, K.B., Malin, B.A., Koenig, B.A., Sanderson, S.C., Rothstein, M.A., & Kullo, I.J. (2013). Ethical, legal, and social implications of incorporating genomic information into electronic health records. *Genetics in Medicine*, *15*(10), 810-816.

[15] O'Daniel, J.M., McLaughlin, H.M., Amendola, L.M., Bale, S.J., Berg, J.S., Bick, D., Bowling, K.M., Chao, E.C., Chung, W.K., Conlin, L.K., Cooper, G.M., Das, S., Deignan, J.L., Dorschner, M.O., Evans, J.P., Ghazani A.A., Goddard K.A., Gornick M., Farwell Hagman K.D., Hambuch T., Hegde M., Hindorff L.A., Holm, I.A., Jarvik, G.P., Knight Johnson, A., Mighion, L., Morra, M., Plon, S.E., Punj, S., Richards, C.S., Santani, A., Shirts, B.H., Spinner, N.B., Tang, S., Weck, K.E., Wolf, S.M., Yang, Y., Rehm, H.L. (2016). A Survey of Current Practices for Genomic Sequencing Test Interpretation and Reporting Processes in US Laboratories. *Genetics in Medicine*, *18*(11).

[16] Rashidkhanova, D.K. (2007). On the legal regulation of the relations concerning the cloning of the human genome. *Medical Law*, 1, 5-10.

[17] Romanovsky, G.B. (2006). Cloning: legal aspects. *Legality*, 1, 50-52.

[18] Romanovsky, G.B. (2013). Constitutional human rights and modern biotechnology. *Constitutional and municipal law*, 5, 27-32.

[19] Romanovsky, G.B. (2017). Constitutional legal personality of citizens in the context of genomic medicine. *Perm University Herald, Jurisprudence*, 3, 260-271.

[20] Robienski, J. (2010). The new law on gene diagnostics in Germany--an overview about the main principles. *Revista de derecho y genoma humano= Law and the human genome review*, (32), 47-68.

[21] Motta-Murguia, L., & Saruwatari-Zavala, G. (2016). Mexican regulation of biobanks. *The Journal of Law, Medicine & Ethics*, *44*(1), 58-67.

[22] Kvachadze, M.O. (1999). Experiments in the field of genetic engineering and legal issues. *Moscow Journal of International Law*, 3, 3-10.

[23] MacFarlane, P., & Kontoleon, B. (2016). Some Legal Issues Regarding the Patenting of Human Genetic Materials. *Journal of law and medicine*, *24*(1), 181-202.

[24] Ajunwa, I. (2016). Genetic Data and Civil Rights. *Harvard Civil Rights-Civil Liberties Law Review*, *51*, 75-114.

[25] Rothstein, M.A., & Rothstein, L. (2016). How genetics might affect real property rights: currents in contemporary bioethics. *The Journal of Law, Medicine & Ethics*, *44*(1), 216-221.

[26] Kokorin, A.P. (2010). To the question of the consent of a surrogate mother to record the child's parents of the spouses who provided their genetic material. *Semeinoe i zhilishchnoe pravo [Family and housing law]*, (1), 28-31.

[27] Pestrikova, A.A. (2015). New aspects of the legal protection of the human genome. *National Association of Scientists*, 6-2 (11), 129-131.

[28] Pestrikova, A.A. (2017). Civil relations involving human biomaterial. *Medical Law*, 4, 32-36.

[29] Gabay, P.G., & Karapetyan, R.Yu. (2017). Compensation for moral harm to injured patients in the Russian Federation: actual problems of theory and practice. *Lawyer*, 20, 40-46.

[30] Suleri, J., & Cavagnaro, E. (2016). Promoting pro-environmental printing behavior: The role of ICT barriers and sustainable values. *International Journal of Education and Development using ICT, 12*(2).

[31] Araya-Guzmán, S., Cares-Monsalves, L., Ramírez-Correa, P., Grandón, E.E., & Alfaro-Perez, J. (2018). Enterprise Architecture Proposal for Undergraduate Teaching in Higher Education Institutions. *Journal of Information Systems Engineering & Management, 3*(3), 21.

[32] Etcuban, J.O., Campanilla, B.S., & Horteza, A.D. (2019). The Use of Mathcad in the Achievement of Education Students in Teaching College Algebra in a University. *International Electronic Journal of Mathematics Education, 14*(2), 341-351.

[33] Semin, A.N., & Kurdymov, A.V. (2018). International food security regulation. *Opción, 34*(85-2), 628-651.