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Defining Practical Importance of Introducing Limitations into the Genome Editing Procedure

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Abstract*: In this article the practical importance of introducing limitations into the genome editing procedure is considered. Diagnostics and editing of the genome provided great opportunities for counteracting many rather serious diseases. However, such clinical work can radically affect a person and his/her further development. In this regard, it is important to balance between the ethical and reasonable component that should be reflected in regulatory legal acts that determine limitations for misuse. In the context of maintaining legal, organizational and other ethical limitations, it is necessary to define their reasonable boundaries for the further development of science and, accordingly, medical care for the population. When writing this 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. In the study it has been concluded that the genome editing naturally generates information about each test subject or patient that must be efficiently protected and rationally used in the future. That is why it is reasonable to start developing limitations aimed at specific gene therapy procedures, in terms of the inadmissibility of intervention in the development of the fetus at the late stages of its growth, which can also be a subject for the further scientific research.

***Index Terms*: genome diagnostics, genome editing, genomic research, legal regulation of genome, limitations of genomic research, use of genome in medicine.**

I. INTRODUCTION

From the beginning the scientific knowledge has mainly been aimed at learning various aspects of the human being. In recent decades, some studies have gone far ahead. It becomes possible not just to study and understand it, but to artificially form a new human being. This aspect is greatly disputed in the society [1], but the modern scientists focus their efforts to a greater extent on the formation of knowledge and methods aimed at ensuring the health of people who have been naturally born. Scientists have learned to transform the DNA, and the latest "genome editing" techniques, such as the CRISPR technology [2], which have repeatedly proven their efficiency, make it possible to reorganize the organism's DNA plan in accordance with the current tasks. There are much more possibilities found in the DNA synthesis ab initio. During the HGP-write project implementation, researchers are going to develop the technologies that will drastically reduce the cost of creating long gene sequences, including the human genome. Thus, technologies in this area are developing much faster than legal norms, which cannot always quickly respond to those clinical developments that can potentially harm a person. Therefore, in addition to observing constitutional human rights, the tasks of medical law also include setting certain limits and restrictions on the spread of fundamentally untested medical activities, both to protect the health of the nation and to maintain the ethical principles of the society.

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II. LITERATURE REVIEW

Many researchers have devoted their works to the human genome editing procedure. In particular, G. R. Abecasis, A. Avton, and D. L. Brooks considered genetic variations and the possibility of editing the genome [3]. P. Andanda, D. Schroeder, S. Chaturvedi, E. Mengesha, and T. Hodges studied the legal framework for the joint use of benefits: from the biodiversity to human genomics [4]. R. Chadwick and K. Berg analyzed new ethical frameworks for genetic databases [5]. J. R. Goldim considered the issues of genetics and ethics when editing the human genome [6]. M. Humbert, E. Ayday and J.-P. Hubaux researched the problem of quantifying the genomic privacy of relatives [7]. In their work R. Isasi, E. Kleiderman, and B. M. Knoppers considered the regulation of genetic technologies [8]. Many other scientists dealt with editing the human genome, but the problem on introducing limitations into the genome editing procedure has been little studied [9], [10].

III. METHODS

A. General Description

Modern world literature abounds with the sources on the need to toughen legislation on introducing a number of limitations into the diagnostics and editing of the human genome.

Nevertheless, the modern technologies must be integrated into the daily lives of citizens. In order to find the balance between the necessary and the reasonable component, the normative legal regulation of several states based on international acts was studied. After that, the main trends and principles that make up the basis for the legislators of various states that use methods of high-tech medicine were identified. Based on this analysis, intermediate conclusions were made. Much attention was paid to the references on the issues under consideration. Based on them, the main trends for setting limitations for genomic medical research and gene therapy were also identified. Having combined the results obtained in the course of such work, general conclusions that are most revealingly reflected in the study results have been made.

B. Algorithm

Due to the pluralistic approach to learning the practical importance of introducing limitations to the genome editing procedure, the most optimal knowledge system was created. It shows objective data on the importance of editing the human genome.

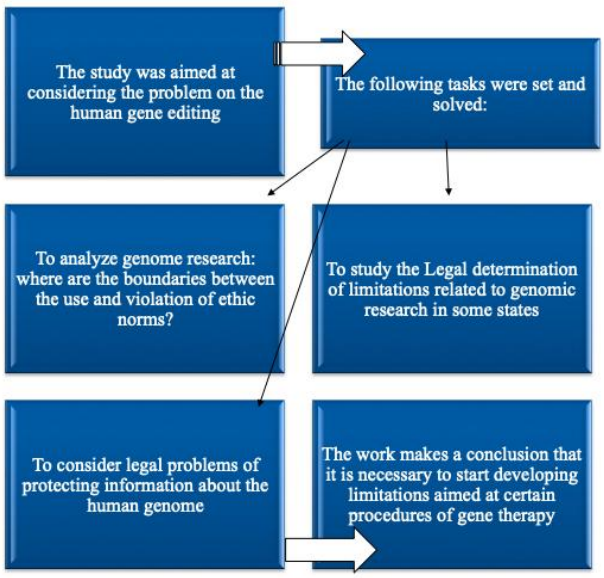
At the stage of collecting and studying singularities, the law interpretation methods were used. They made it possible to define the evidentiary presumption of the need to introduce limitations in the human genome editing.

The prognostic method allowed to make scientifically based predictions about applying certain requirements to genome editing and to develop recommendations for the law enforcement practice. Besides, in addition to the above methods, the logical-semantic analysis was used. It allowed considering details of introducing limitations in the human genome editing.

C. Flow Chart

In the study certain algorithms were used. *Table I. Study Algorithm* shows the study algorithm.

Table I. Study Algorithm



IV. RESULTS AND DISCUSSIONS

The legislation of various countries differently regulates the area of scientific knowledge and its humanitarian component. For ethical reasons, it is better not to intervene in the human genome at all, and let people develop independently. However, many people objectively need any means of medical intervention to get help, and in this case the ethical component should become secondary. Such approach should be legally regulated.

When improving legal norms, it is necessary to take into account all interests of citizens that arise, the possibility to influence children with pathologies, the degree of state participation in this process to maintain the health of the nation, defining the subjects who can be given genomic information, etc. At the same time, the persons participating in experimental studies, even if they pursue only their own interests, must rely on the subsequent preferential therapeutic and rehabilitation support.

When carrying out genomic research, the obtained information is of great importance. The work related to the diagnosis and editing of the human genome should be carried out only if it is legally regulated and there are strict requirements for the protection of such information provided by biobanks, and this information should be well protected throughout the entire period of its existence. State bodies should be prohibited to collect genomic data of citizens without their knowledge or consent, except the cases when it threats public safety. Otherwise, it violates a number of human rights.

It is necessary to solve the issue of ownership of genomic materials during various stages of the relevant research. The results of this work will help to determine the legal power of subjects of legal relations regarding the provision of information about the genome, its further use, the legality of state or other intervention in the above procedures.

Taking into account these components, it is necessary to set legal limitations on the diagnosis and editing of the human genome, which can protect the rights and legal interests of the individual, without affecting the modernization of scientific knowledge and improving the efficiency of the medical activity.

1. Genomic Research: Where is the Boundary between Use and Violation of Ethic Norms?

Despite the emerging prospects and resonance in the scientific community, the success of genomic research did not evoke complete unanimity [11]. In terms of ethics, the HGP-write project has already determined a great number of questions. After all, the access to a fully engineered artificial genome provides unimaginable possibilities for the artificial creation of people whose social status, as well as the only belonging to the society is under question (Scientists announced the launch of the HGP-write project whose ultimate goal is to states it is prohibited to carry out screening because of create a full synthetic human genome, 2018).

Taking into account the fact that the initial research projects on the diagnosis and editing of the human genome were international, it is not enough to provide regulation within states.

Such regulation will eventually narrow down to the prohibition of such research in some countries, which, on the one hand, is inefficient in the context of many peripheral and other territories that formally belong to other states. On the other hand, it restrains the development of scientific knowledge. Ways of overcoming cancer and other incurable diseases are found behind everything that is unethical and unnatural [12].

There are also problems related to diagnosing and editing a "biological" genome. Firstly, these procedures are performed mainly with children or unborn babies in their mothers' womb [13]. Secondly, the medical intervention under consideration is carried out in relation to people with certain developmental disorders, pathological diseases, etc. Genome editing is the artificial formation of part of cellular elements for the subsequent positive development of the organism. However, at present, few people can guarantee the indispensable success after these actions, as well as that editing the genome will not form a new pathology. "Programming" the genome, physicians proceed from the current conditions, but the ecology and the socio-economic situation are not stable, and the human psychology is transformed due to the age, etc. [14]. In any case, this is a great risk to take a decision about the operation. It is most often taken by the parents of children who then grow up and cannot do anything with the decision taken for them earlier.

There is an opinion that the development of the human genome editing will cause a sort of "subhuman beings" [15]. Genetic construction does not allow forming a person in the full philosophical sense of the word. Moreover, there are fears that society may be divided into ordinary and artificially created people. Such technologies are dangerous because they can be used by the parents who want their child to look in a special way or, by their physiological properties, be able to choose the profession parents were not capable of. The above conditions limit the freedom of the person's choice formed by using scientific achievements [16]. Others believe that any intervention with the child's genes violates his/her rights and turns him/her into a "genetic prisoner" [17]. Finally, C.P. Neuhaus considers the threat to the whole mankind caused by the development of the human genome [18].

2. Legal Setting Limitations on Genomic Research in Some States

States have various approaches to genomic research in medical practice. Simple procedures such as non-invasive prenatal genetic testing cause a lot of ethical, legal and social questions among modern researchers [19]. At the same time, some countries adopt state programs for the mandatory activities to be performed by all young mothers [20]. Along with this, based on the nationwide Constitution, the United States have developed the legal mechanisms that allow administrative use of NBS technologies aimed at preventing the emergence of sick people, primarily with mental disabilities [21].

The above situation has a double contradiction. On the one hand, the constitutional and legal regulation in the United States of America allows an adult to independently manage his/her health and take a decision on the genomic diagnostics. Besides, the legislation of this state allows parents to solve a number of issues related to their children's life. However, the judicial practice (taking into account the fact that the United States have a precedent legal system) allows the interference in the minor's life without taking into account the opinion of his/her parents when it comes to the interests of the society and the state [22]. As a result, the practice of applying this procedure varies depending on a state. Therefore, in some religious or philosophical beliefs of parents if they directly declare this [20]. The Brazilian regulatory documents have something similar in the legal regulation [23].

The legislation on the human genome editing varies in different countries: from the complete prohibition to intermediate or permissive regulation of the area under consideration to support scientific progress, subject to the appropriate control [8].

Back in 2015, the UK lifted the prohibition on certain gene therapy procedures to prevent serious diseases that, according to some estimates, threatened the state to become an outcast in the world community in terms of bioethics [24]. The United States of America allow some procedures related to the human genome editing, although the state budget does not finance it [25], which allows developing the private sector in this area that pursues only the commercial interest and makes human health and rights secondary.

Some countries additionally prohibit the genome editing in relation to embryos after the fourteenth day of their development, which presumably is the stage of forming the necessary physiological signs of a developing person [26]. This rule is based on the peculiarities of the nervous system and some other medical factors [27]. Moreover, this specificity has essential impact on the embryo immediately after its formation. After such risks had become publicly known, there were ideas about the total prohibition on editing the human genome at this stage [28]. However, by now most countries have not done it. Over the past few years, two different laboratories have reported successful work done until the thirteenth day after the fertilization, developing the disputes on reconsidering the 14-days rule [29].

The emerging trend in carrying out gene therapy outside specialized medical institutions has become a serious problem in recent years. In particular, the Japanese law allows such possibility, and the UK has got a mechanism for licensing this activity performed by private companies [30]. Meanwhile, many scientists and public figures oppose this practice, and believe that due to the commercialization of this process, the human genome editing technologies stimulate the establishment of many clinics providing the relevant services that are not actually controlled by the state and other competent structures [31].

This situation should change in terms of strengthening the state control over this activity and the introduction of a number of limitations on the commercialization of diagnostics and editing the human genome against the constantly decreasing prices for these procedures.

3. Legal Problems of Protecting Information about the Human Genome

Today the development of genomic research causes a number of nonbiological threats.

The constant reduction in prices of technologies that allow diagnosing the human genome makes it possible to illegally obtain information as a result of such study due to the availability of sequencing and the possibility of carrying it out in relation to many people almost simultaneously [3]. When sequencing the genome, the information about the parents' nationality and the susceptibility of all relatives to certain diseases becomes available [7]. This can affect other individuals who did not even suspect about any genetic research carried out earlier with respect to their relatives. If a young man who has proved to have excellent health at the initial medical examination wants to apply to any specialized law enforcement agencies, the latter can hypothetically find and use information about the physiological negative predisposition, including of his/her relatives whose genome has previously been diagnosed. As a result, the healthy man who is suitable for service can lose the desired career only because of the deviations found during the diagnostics of his/her parents' genome. Of course, this situation is modeled and the law enforcement agencies of most states do not have formal grounds for refusing to hire such a person. However, there are such cases in practice [32], and they can violate the confidentiality of information on the results of the human genome diagnostics. Such confidential information can be disclosed in many ways: from mere data exchange between different laboratories or organizations required for the research [33] to the illegal collection of these data and subsequent speculation for mercenary purposes. Analyzing legal variants for the exchange of genomic data, a number of modern scientists develop the concept of benefit-sharing that involves the mutual exchange of the necessary benefits [34]. With regard to the subject of this study, it will be implemented according to the following scheme: some researchers provide other researchers with the open genomic data, the latter through this act get the right to require the genomic data they need regardless of their secrecy if they have the properties required for the research. The international legal regulation allows such activities [4], but the issue of the safety and security of the relevant information remains unsolved. Several years ago, some US states allowed sampling genomic data of people during the arrest in the interests of the investigation and state security [35]. Thus, law enforcement agencies collect additional data on the nuisancer, which is inconsistent with the fundamentals of bioethics because in addition to visual, documentary and other information about a person, the state actually keeps a part of his/her body.

Besides, it is necessary to take into account that the protection of such information was legally regulated much later than it had started being collected. Far from all countries solved the issue on treating the information under consideration [6]. As a result, there can be a situation when old genomic information is not protected by efficient protection measures, which may cause its unauthorized distribution, including among lawbreakers. Nowadays some countries form specialized biobanks to store genomic information. For example, Denmark applies rather strict rules to such formations, and they are defined in regulatory legal acts of the relevant states [34]. According to the authors, every state that carries out genetic research must obligatorily create biobanks with unprecedented measures to protect information. It is reasonable to directly prohibit the genome diagnostics if there are no biobanks protected at the international level.

4. Setting the Problem on Defining Limitations for Genomic Research

As mentioned above, genomic research may be applied in various areas of the society, which causes even a greater number of problems to be solved by legal means. Thus, in the pharmaceutical activity, it is very difficult to define whether the contribution of those people whose genomic material was useful for pharmacy is significant [5]. This uncertainty logically raises the question about the person's ownership of the genomic material located or that has been found in his/her body. The next ethical and legal issue is to define the owner of the elements of one person transferred to and adopted in the body of another [36]. Some problems arise after organizing the relevant activity. It is often difficult to achieve a positive result due to a number of objective factors. One of them is the inability to combine scientific research and patient treatment during the genomic research [37].At the same time, it is necessary to note that from the medical point of view, it is impossible to efficiently treat all diseases by genome editing. Thus, scientists disagree on whether any disease is due to pathology [38]. It is possible that the genomic intervention will be useless or will not bring the desired result – for example, it will not remove the problems of the human predisposition to certain diseases because it is not due to pathology. This aspect should also be taken into account, both when formulating norms of the current law and when parents take a decision on genetic procedures for their child.Finally, diagnostics and more than that – the genome editing naturally form the information about each test subject or patient that must be efficiently protected and rationally used in the future.

V. CONCLUSION

Today medicine is developing quite rapidly, and many diseases can be treated without interfering with the human genome. However, if it is carried out, it is necessary to combine peculiarities of the doctor's and clinician's work. The latter is applied to laboratory tests due to the specifics of diagnostics and, moreover, genome editing [13]. While the ordinary medicine works by the following scheme: the doctor does the main work, and laboratory tests help him/her to solve the key problem, in this case the situation should be opposite: the clinician should do his/her work being constantly assisted by a therapist. This approach against the optimization of regulatory legal framework can implicitly positively influence the correct application of genome diagnostics and editing for the benefit of the whole world, help those in need, and make breakthrough medical discoveries without considerably affecting the ethical component of the issue under consideration. It is also necessary to start developing limitations aimed at certain procedures of the gene therapy in terms of the inadmissibility to intervene in the development of the fetus in the late stages of its growth, which can also be a subject of the further scientific research.

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