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PROSPECTS FOR HUMAN GENOME EDITING: CHALLENGES OF LEGAL REGULATION

Abstract. Gene editing technologies are developing at ever-increasing pace. A large number of scientific publications on the progress, existing problems and prospects of human genome editing indicate high expectations for the advancement of research in this area and the possibilities of modifying the human genome, for example, for medical purposes. The intensive development of genome editing technologies opens up revolutionary possibilities for widespread use and at the same time creates uncertainty and fear of the human genome editing's consequences. The problems of legal regulation in this area are largely related to a number of bioethical issues related to human genome editing, namely the ethics and limits of interference with human nature and the possibility of changing it.

The article aims to study the legal regulation of human genome editing, identifying the undetermined aspects of it with further steps to propose the solution considering the necessity to protect the fundamental human right to health care that could benefit from the application of such technologies.

USA, Australia, New Zealand and a considerable number of the EU countries' national acts prohibit human germline editing. Legal provisions to prohibit such actions are explained by the fact that humanity currently does not have sufficient knowledge about the possible consequences of editing the germline and fears are raised that the modification of the genome which could be passed on to future generations may lead to practices that violate human rights and undermine the principles of respect for human dignity, justice, and equality.

The analysis showed that legal regulation of human genome editing needs to be improved in Ukraine. The complex approach is required to form a legislative framework considering different aspects of the application of human genome modification that were analyzed in the article, namely:

– as a component of the right to health through the use of biotechnology in medicine and pharmacy, gene therapy, and ensuring wide access to effective methods and means of preventing, diagnosing, and treating diseases;

– as the fulfillment of the duty of the state to preserve the gene pool of the Ukrainian people;

– as an element of national security (in particular biosecurity) to assess the risks of editing the human genome as a technology to improve (or worsen) human potential with the subsequent development of policies, including legal, to identify/prevent/confront possible risks;

– in the context of intellectual property development to stimulate investment and innovation in science, taking into account the priority of fundamental human rights.

Keywords: human genome editing; access to treatment; intellectual property; bioethics; right to health care.

The global market value of genetic engineering and its profit in proportion is estimated at 1400 million US dollars in 2023. It is expected to hit the level of 1491,6 million US dollars in 2024 with the anticipated level of profit of 2917,2 million in 2033, which compound annual growth rate of about 6.74% between the years 2024 and 2033[1].

In 2020, the Nobel Prize in Chemistry was awarded to two scientists, Emmanuel Charpentier, and Jennifer Doudna, for the discovery of the genome editing method CRISPR/Cas9, commonly known as "genetic scissors"[2].

CRISPR (Short Palindromic Repeats regularly formed in groups) is a technology of selective DNA modification of living cells. This technology is called "genetic scissors", because of the core ability to break any DNA chain in a certain place in such a way as to "eliminate the unnecessary fractions". The Cas9 (CRISPR-associated) protein cleaves (or cuts) the DNA at the right place.

The therapy based on CRISPR gene editing technology was authorized in the UK in 2023 for the treatment of sickle-cell disease and transfusion-dependent beta thalassaemia[3]. Along with that, on December 8, 2023, the US Food and Drug Administration (FDA) approved Casgevy, an innovative CRISPR-based gene editing therapy from Vertex Pharmaceuticals and CRISPR Therapeutics, for the treatment of sickle cell anemia (SCD)[4].

The intensive evolution of genome editing technologies enhances the opportunities for the wide exploitation of the technology and accordingly generates uncertainty and fear related to the consequences of such exploitation for humanity. The interest in genome editing is shown by multiple conferences, summits, and round tables held worldwide[5].

The legal regulation issues that arise are related to the bioethical aspects of human genome editing, mainly to the actions of intervention into the human genome, the nature, and the ethical measures of this process. The protection of intellectual property rights for inventions in the field of human genome editing is

[1] [Latest] Global Genetic Engineering Market Size/Share Worth USD 2,917.2 Million by 2033 at a 6.74% CAGR: Custom Market Insights (Analysis, Outlook, Leaders, Report, Trends, Forecast, Segmentation, Growth, Growth Rate, Value) <https://www.globenewswire.com/news-release/2024/08/09/2927525/0/en/Latest-Global-Genetic-Engineering-Market-Size-Share-Worth-USD-2-917-2-Million-by-2033-at-a-6-74-CAGR-Custom-Market-Insights-Analysis-Outlook-Leaders-Report-Trends-Forecast-Segmenta.html> (accessed 07.02.2025).

[2] Nobel Prizes 2020 <https://www.nobelprize.org/all-nobel-prizes-2020> (accessed 07.02.2025).

[3] UK medicines regulator approves world-first gene-editing treatment for blood disorders <https://www.imperial.nhs.uk/about-us/news/uk-medicines-regulator-approves-world-first-gene-editing-treatment-for-blood-disorders> (accessed 07.02.2025).

[4] Kevin Davies, 'FDA Approves Casgevy, the First CRISPR Therapy, for Sickle Cell Disease' <https://www.genengnews.com/topics/genome-editing/fda-approves-the-first-crispr-therapy-for-sickle-cell-disease> (accessed 07.02.2025).

[5] Third International Summit on Human Genome Editing <https://royalsociety.org/science-events-and-lectures/2023/03/2023-human-genome-editing-summit> (accessed 07.02.2025); M J Legato, G M Church, H T Greely et al, 'Editing the Human Genome: Progress and Controversies' [2017] 1(1) Gender and the Genome 4–11 doi:10.1089/gg.2016.29001.rtl; Gabriela Ilian Ramos, 'Ethics of the Genome Editing Roundtable' (February 11, 2022) <https://gabrielailianramos.wordpress.com/2022/02/11/ethics-of-the-genome-editing-roundtable> (accessed 07.02.2025); Roundtable on the ethics of gene editing, Brussels <https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vl1ea9cge3qm?ctx=vg9pir5eze8o&v=1&tab=2&n=23> (accessed 07.02.2025).

an important aspect in this regard, specifically in the context of compliance with generally recognized principles of morality, as well as in the context of the possible abuse of patent rights for such inventions.

The scientific research of the legal framework of human genome editing was recently held by H. Krushelnytska, O. Piddubnyi, B. C. van Beers, L. Wang, D. Kim, and others.

Given the expectations and prospects of the scientists about the further development and possibilities of using genetic engineering tools for editing the human genome, it is necessary to investigate the legal regulation of the modification of the human genome and the prospects for further legislative changes in this area.

The article aims to study the legal regulation of human genome editing, identifying the undetermined aspects of it with further steps to propose the solution considering the necessity to protect the fundamental human right to health care that could benefit from the application of such technologies.

Article 1 of the Universal Declaration on the Human Genome and Human Rights adopted 11 November 1997 (hereinafter – Declaration) states: 'The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity'[6].

The USA National Human Genome Research Institute identifies genome as 'the entire set of DNA instructions found in a cell. In humans, the genome consists of 23 pairs of chromosomes located in the cell's nucleus, as well as a small chromosome in the cell's mitochondria'[7].

Article 13 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (hereinafter – Convention) states: 'an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants'[8].

Giving the importance of the CRISPR/Cas9 technology, The European Commission declares: 'However, the application of genome editing technologies to human gametes or embryos raises many ethical, social and safety issues, particularly from any modification of the human genome which could be passed on to future generations'[9].

[6] Universal Declaration on the Human Genome and Human Rights <https://www.unesco.org/en/legal-affairs/universal-declaration-human-genome-and-human-rights?hub=387> (accessed 07.02.2025).

[7] Genome <https://www.genome.gov/genetics-glossary/Genome > (accessed 07.02.2025).

[8] Конвенція про захист прав і гідності людини щодо застосування біології та медицини від 04.04.1997 <https://zakon.rada.gov.ua/laws/show/994_334#Text> (дата звернення 07.02.2025).

[9] Ethics and Human Rights must guide any use of genome editing technologies in human beings: Statement by the Council of Europe Committee on Bioethics. 30 November 2018 <https://www.coe.int/en/web/portal/-/ethics-and-human-rights-must-guide-any-use-of-genome-editing-technologies-in-human-beings-> (accessed 12.02.2025).

A considerable number of the EU countries' national acts obtain a provision to prohibit human germline editing[10]. Additionally, such interference is prohibited by the Congress acts[11]. Australia prohibits of human germline editing as established by The Prohibition of Human Cloning for Reproduction Act 2002[12]. New Zeland prohibits of human germline editing under guidelines set by the Health Research Council of New Zealand[13].

Legal provisions to prohibit such actions are explained by the fact that humanity currently does not have sufficient knowledge about the possible consequences of editing the germline and fears are raised that the modification of the genome which could be passed on to future generations may lead to practices that violate human rights and undermine the principles of respect for human dignity, justice, and equality. Article 10 of the Declaration sets out that no research or research applications concerning the human genome, in particular in the fields of biology, genetics, and medicine, should prevail over respect for the human rights, fundamental freedoms, and human dignity of individuals or, where applicable, of groups of people[14].

However, Britta C van Beers highlights that the meaning of human rights and their underlying principles can change over time, referring to the European Court of Human Rights' application of the provisions of the European Convention as:

> living instrument, which must be interpreted in the light of present day conditions, even when it comes to core human rights such as the prohibition on torture and inhuman or degrading treatments or punishments. The same line of thinking necessarily applies to the principles underlying these rights, such as human dignity[15].

The Steering Committee for Human Rights in the fields of Biomedicine and Health (CDBIO) clarified Article 13 of the Convention stating the following: the prohibition of an intervention seeking to introduce a modification in the genome of any descendants implies that gametes, embryos or their precursors that have been subjected to such intervention may not be used for procreation. In the context of research, interventions seeking to modify the human genome for the acquisition of knowledge relevant to the permitted purposes may be carried out with preventive, diagnostic, or therapeutic purposes[16].

[10] Information on the situation regarding the use of CRISPR-Cas9 technology, in particular with a view to the possible modification of the genetic characteristics of an embryo or germline, in the light of Article 13 of the Oviedo Convention. <https://rm.coe.int/1680475c91#_Toc431300658> (accessed 12.02.2025).

[11] United States: Germline / Embryonic <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/united-states-embryonic-germline-gene-editing> (accessed 12.02.2025).

[12] Australia: Germline / Embryonic <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/australia-germline-embryonic> (accessed 12.02.2025).

[13] New Zealand: Germline / Embryonic <https://crispr-gene-editing-regs-tracker.geneticliteracyproject.org/new-zealand-germline> (accessed 12.02.2025).

[14] Universal Declaration on the Human Genome and Human Rights (n 6).

[15] B C van Beers, 'Rewriting the human genome, rewriting human rights law? Human rights, human dignity, and human germline modification in the CRISPR era' [2020] 7(1) The Journal of Law and the Biosciences 1–36.

[16] Intervention of the Human Genome Re-examination Process of Article 13 of the Oviedo Convention. Conclusions and clarifications <https://rm.coe.int/cdbio-2022-7-final-clarifications-er-art-13-e-/1680a8736c> (accessed 12.02.2025).

Although Ukraine signed the Convention in 2002, it still remains unratified, thus there is no certainty at the Ukrainian national legislative level regarding the legal limits of the modification of the human genome, including germline.

Taking into consideration the limited national legal framework it is worth to start analyzing the national provisions from the opposite, that is, not what is prohibited, but what is allowed. Subsection. 3.12. of The Procedure for the Use of Assisted Reproductive Technologies in Ukraine (hereinafter – the Procedure) sets out the further protocol: after the completion of the fertilization cycle, if there are any remaining unused oocytes/embryos, the patient can make a decision to use these oocytes/embryos for treatment programs of other patients, and section V of the Procedure provides for the conditions of embryo donation[17]. So, the unused embryos cannot be used for research purposes.

Article 10 of the Law of Ukraine "On Medicinal Products"[18] dated 28.07.2022 prohibits clinical trials in the field of gene therapy that lead to a change in the genetic identity of subjects through the germline, but most of the provisions of this law will be enacted 30 months after the end of martial law in Ukraine. This provision of Ukrainian legislation is identical to the provision of Article 90 of Regulation (EU) No 536/2014[19]. However, the scope of both legal acts is limited to legal relations regarding all stages of creation and marketing of medicinal products, i.e., the purposes of therapy, but the potential for germline modification is not limited to such purposes.

Editing the human genome for the purpose of prevention, diagnosis, or treatment, as provided for in Article 13 of the Convention, can be considered in the context of the human right to health protection. The preamble of the Constitution of the World Health Organization states that enjoyment of the highest attainable standard of health is one of the fundamental rights of every person regardless of race, religion, political beliefs, economic or social status, defining health as a state of complete physical, mental and social well-being, and not simply the absence of illness or physical disability[20].

We support the scientific position that the right to health depends on and contributes to the realization of many other interrelated rights, among other things – the right to enjoy the benefits of scientific progress[21]. Applying the right to health in a broader context provides the possibility to access all available scientific

[17] Про затвердження Порядку застосування допоміжних репродуктивних технологій в Україні: наказ Міністерства охорони здоров'я України від 09.09.2013 № 787 <https://zakon.rada.gov.ua/laws/show/z1697-13#Text> (дата звернення 12.02.2025).

[18] Про лікарські засоби: Закон України від 28 липня 2022 р. № 2469-IX <https://zakon.rada.gov.ua/laws/show/2469-20#Text> (дата звернення 12.02.2025).

[19] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC <https://eur-lex.europa.eu/eli/reg/2014/536/oj/eng> (accessed 12.02.2025).

[20] Constitution of the World Health Organization <https://apps.who.int/gb/bd/pdf/bd47/en/constitution-en.pdf> (accessed 12.02.2025).

[21] L Wang, X Liang, W Zhang, 'Genome editing and human rights: Implications of the UNGPs' [2022] 4(6) Biosafety and Health 386–391.

innovations, and new technologies in medicine and pharmacy; in such a way as to achieve the enjoyment of the highest attainable standard of health. Accordingly, the General Comment No. 14 UN Committee on Economic, Social and Cultural Rights (CESCR) states that the human right to health is provided by the states to anyone who is under the country's jurisdiction[22].

The human genome editing technologies' progress stimulates the need to adopt proper legislation, which should also be considered in regard to fulfillment of the state's obligations to preserve the Ukrainian gene pool. Article 16 of the Constitution of Ukraine[23] establishes that the preservation of the gene pool of the Ukrainian nation is the responsibility of the state. This duty is more broadly consecrated in Art. 29 of the Law of Ukraine "Fundamentals of Ukrainian legislation on health care" (hereinafter – Fundamentals), which states:

> taking into account the preservation of the gene pool of the Ukrainian nation, the prevention of the demographical crisis, the need to provide the right to health for future generations, and to effectively prevent hereditary diseases the state forms a list of actions to eliminate the cause that harms the genetic apparatus, and also creates a system of state genetic monitoring, organizes medical and genetic assistance to the population, contributes to the enrichment and dissemination of scientific knowledge in the field of genetics and demography. Medical intervention that can cause a disorder of the human genetic apparatus is prohibited[24].

Despite the lack of clear provisions about what actions the state should take to preserve the gene pool of the Ukrainian nation, Article 29 of the Fundamentals states that the state should:

– implement measures aimed to eliminate factors that adversely affect the genetic apparatus of a person;
– create a system of state genetic monitoring;
– provide medical and genetic assistance to the population;
–- contribute to the enrichment and dissemination of scientific knowledge in the field of genetics and demography.

The above-mentooned tasts to preserve the pool of the Ukrainian nation require a set of actions to be implemented, based on the scientific progress in the field of genetics and further application of its achievements into medicine and pharmacy by providing the population with access to effective means and methods of prevention, diagnosis, and therapy.

Taking into account the challenges for Ukraine and the terrible consequences of the war, including demographic consequences, and given the intensity of the

[22] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4) <https://www.refworld.org/legal/general/cescr/2000/en/36991> (accessed 12.02.2025).

[23] Конституція України від 28 червня 1996 року <https://zakon.rada.gov.ua/laws/show/254%D0%BA/96-%D0%B2%D1%80#Text> (дата звернення 12.02.2025).

[24] Основи законодавства України про охорону здоров'я: Закон України від 19 листопада 1992 р. № 2801-XII <https://zakon.rada.gov.ua/laws/show/2801-12#Text> (дата звернення 12.02.2025).

development of biotechnology in medicine and pharmacy and the prospects for gene therapy[25] we support H. L. Krushelnytska,

> attention should be paid to the revision of the outdated legislation on medical and genetic held to create a favorable legal framework (especially the financial one) for using the latest biomedical technologies for editing the human genome, which will allow the identification and curation of genetic diseases[26].

Unsurprisingly, such a vulnerable topic as editing the human genome, especially germline, is subject to active discussion among the biologists and geneticists but also among the broader public, lawyers, politicians and policymakers etc. The core concern is that these technologies although having great potential for curation of disease, cause at the same time the potential to get the manipulations out of control with unpredictable consequences.

The scientists warn that cell engineering as well as other genetic technologies have the possibility to manipulate with human genome that potentially could be used outside of medical purposes[27].

A. R. Badea and O. Feeney, forewarn about the potential danger of double use of human genome editing, especially for military purposes:

> At national level, states need to adapt their domestic (bio)security and defence strategies to include genome editing as a possible threat (with conceivable WMD potential). Threat-awareness and risk-assessment are the first steps towards building a comprehensive (bio) security framework, which can later be backed up by mechanisms of detection, prevention and response to malicious acts involving genome editing activities[28].

This conclusion is important for Ukraine in regard to the ongoing war and aggression from the russian federation. By adopting The Biological Security and Biological Protection Strategy (the decision of the National Security and Defence Council of Ukraine of October 15, 2021, which was put into effect by Decree of the President of Ukraine on December 17, 2021 No. 668/2021) Ukraine declared:

> there exists a trend of the increase of the negative effects of the biological factors on the population and on the environment, the biological threats were derived from the development of the biotechnology and synthetic biotechnology migration processes, transboundary movements of animals, goods, the emergence of new pathogens of emergent infections,

[25] B Cetin, F Erendor, Y E Eksi, A D Sanlioglu, S Sanlioglu, 'Gene and cell therapy of human genetic diseases: Recent advances and future directions' [2024] 28(17) Journal of Cellular and Molecular Medicine 1–15; Y Kim, A P Landstrom, S H Shah, J C Wu, C E Seidman, 'Gene Therapy in Cardiovascular Disease: Recent Advances and Future Directions in Science: A Science Advisory From the American Heart Association' [2024] 150(23) Circulation 471–480.

[26] Г Крушельницька, 'Економіко-правові засади медико-генетичної допомоги в Україні' [2024] 3 Київський часопис права 150–157 https://doi.org/10.32782/klj/2024.3.22

[27] О Піддубний, Д Маріц, В Єгорова, Т Чепульченко, О Владикін, 'Етичні та правові аспекти редагування генома пацієнта в немедичних цілях' [2023] 6(4) Соціально-правові студії 174–182.

[28] A R Badea, O Feeney, 'Genome Editing Dilemma: Navigating Dual-Use Potential and Charting the Path Forward' [2024] Bioethical Inquiry https://doi.org/10.1007/s11673-024-10358-8.

> manifestations of bioterrorism, the lack of a well-defined procedure for conducting genetic engineering activities, etc[29].

The above-mentioned together with the Ukrainian own experience of the violation of human rights by the country-aggressor, which ignores the international law and the rules of conducting the war, convict of the existing risk of potential unlawful use of human genome editing for military purposes. The legal regulation of genome editing and the protection of IP rights are important in this regard.

Based on the example of CRISPR/Cas the researchers note that there is a likelihood of regular patent dependencies on additional technologies, linked to CRISPR/Cas, like delivery systems in specific cells and organisms[30]. We believe that in the context of barriers that may arise in connection with the protection of patent rights in the field of modification of the human genome, it is necessary to proceed from the goals and objectives for which patented technologies will be used.

It is worth mentioning, that when national security interests are at risk (for example the conservation of the gene pool of the Ukrainian nation in terms of prevention from hereditary diseases) it is possible to address the matter based on provisions of the international agreements, such as Article 31 Compulsory Licensing and Article 73 Security Exceptions of The Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS)[31].

The Law of Ukraine "On the Protection of Rights to Inventions and Utility Models"[32] prohibits to patent the processes of changing the genetic identity of people through the germline. The Ukrainian legislation was supplemented with this provision in the course of reforming the patent protection system, in particular in the field of pharmacy and medicine in 2020.

Ukraine is currently harmonizing its legislation in accordance with the EU legal norms approaching its final goal to join the EU. In this regard, the EU approach toward the regulation is important, the EU Parliament in the survey "Genome editing in humans: A survey of law, regulation and governance principles" states:

> legality and increase legal certainty. Indirectly, coherence also fosters good governance, compliance, and enforcement. However, on one hand in matters of regulating genome editing where there are a plurality of ethical understandings and social concerns in the EU Member States, legal pluralism may well be a necessity[33].

[29] Про Стратегію біобезпеки та біологічного захисту: рішення Ради національної безпеки і оборони України від 15 жовтня 2021 року <https://zakon.rada.gov.ua/go/n0079525-21> (дата звернення 12.02.2025).
[30] D Kim, R Hilty, E Hofmeister, P R Slowinski, M Steinhart, 'CRISPR/Cas Technology and Innovation: Mapping Patent Law Issues' [2022] 22-06 Max Planck Institute for Innovation & Competition Research Paper 1–49.
[31] Угода про торговельні аспекти прав інтелектуальної власності від 15.04.1994 <https://zakon.rada.gov.ua/laws/show/981_018> (дата звернення 12.02.2025).
[32] Про охорону прав на винаходи і корисні моделі: Закон України від 15 грудня 1993 р. № 3687-XII <https://zakon.rada.gov.ua/laws/show/3687-12#Text> (дата звернення 12.02.2025).
[33] Genome editing in humans. A survey of law, regulation and governance principles <https://www.europarl.europa.eu/RegData/etudes/STUD/2022/729506/EPRS_STU(2022)729506_EN.pdf> (accessed 12.02.2025).

To be noted, the absence of a clear legislative framework, mainly on the modification of the germline, does not protect this area from potential manipulations, but on the contrary, creates additional grey zone and uncertainty with more ethical and legal risks.

Conclusions. The analysis showed that legal regulation of human genome editing needs to be improved in Ukraine. The complex approach is required to form a legislative framework considering different aspects of the application of human genome modification that were analyzed in the article, namely:

– as a component of the right to health through the use of biotechnology in medicine and pharmacy, gene therapy, and ensuring wide access to effective methods and means of preventing, diagnosing, and treating diseases;

– as the fulfillment of the duty of the state to preserve the gene pool of the Ukrainian people;

– as an element of national security (in particular biosecurity) to assess the risks of editing the human genome as a technology to improve (or worsen) human potential with the subsequent development of policies, including legal, to identify/prevent/confront possible risks;

– in the context of intellectual property development to stimulate investment and innovation in science, taking into account the priority of fundamental human rights.

Editing the human genome inevitably generates significant ethical and legal controversies. The development of the necessary legislative changes requires prior consultations of a wide range of specialists from different areas, a balanced approach to the establishment of legal restrictions and permits is needed. The achievements of science and technology should contribute to ensuring fundamental human rights, safeguarding at the same time the principles of justice and equality. Legal certainty in the field of human genome editing at the national level should cover at least legally established limits on key aspects (especially on the admissibility/prohibition of germline modification for the purpose of reproduction and/or research, legal approaches to the protection of intellectual property rights for inventions in this area, etc.) in order to protect fundamental human rights and public interests in the field of health.

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ПЕРСПЕКТИВИ РЕДАГУВАННЯ ГЕНОМА ЛЮДИНИ: ВИКЛИКИ ПРАВОВОГО РЕГУЛЮВАННЯ

Анотація. Технології редагування генів розвиваються дедалі швидшими темпами. Велика кількість наукових публікацій щодо поступу, існуючих проблем і перспектив редагування генома людини свідчить про вагомі очікування щодо просування досліджень у цій сфері та

можливостей видозміни генома людини, наприклад, у медичних цілях. Інтенсивний розвиток технологій редагування генома відкриває людству революційні можливості широкого застосування і заодно породжує невизначеність та страх перед наслідками редагування генома людини. Проблеми правового регулювання у цій сфері значно пов'язані з низкою біоетичних питань щодо редагування генома людини, а саме щодо етичності та меж втручання у людську природу та можливостей її зміни.

Мета статті полягає у дослідженні законодавства щодо правового регулювання редагування генома людини, виявлення проблемних аспектів та формування пропозицій щодо їх усунення з урахуванням необхідності забезпечення фундаментального права людини на охорону здоров'я.

Національні законодавства багатьох країн ЄС, а також США, Австралії, Нової Зеландії містять заборони на редагування зародкової лінії. Законодавче закріплення таких заборон пояснюється тим, що наразі людство не має достатніх знань про можливі наслідки редагування зародкової лінії і побоюваннями, що видозміна генома нащадків може призвести до практики, яка суперечить правам людини та підриватиме принципи поваги до гідності людини, справедливості та рівності.

Проведений аналіз засвідчив, що національне законодавство України потребує удосконалення правового регулювання редагування генома людини. Законодавчі зміни необхідно впроваджувати шляхом комплексного підходу урахування аспектів застосування видозміни генома людини:

– як складової права на охорону здоров'я через застосування біотехнології у медицині та фармації, генної терапії і забезпечення широкого доступу до ефективних методів та засобів попередження, діагностики, лікування хвороб;

– як виконання обов'язку держави щодо збереження генофонду Українського народу;

– як елемент національної безпеки (зокрема біобезпеки) щодо оцінки ризиків редагування генома людини як технології покращення (або погіршення) людського потенціалу з подальшим розробленням політики, у т. ч. правової, щодо виявлення / попередження / протистояння можливим ризикам;

– у контексті розвитку сфери інтелектуальної власності для стимулювання інвестицій та інновацій у науці з урахуванням пріоритету основоположних прав людини.

Ключові слова: редагування генома людини; доступ до лікування; інтелектуальна власність; біоетика; право на охорону здоров'я.