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INTERNATIONAL LEGAL ASPECTS OF HUMAN LIFE PROTECTION IN THE PROCESS OF APPLICATION OF INNOVATIVE BIOMEDICAL TECHNOLOGIES



Introduction. *The development of innovative biomedical technologies and the dissemination of biomedical services, as well as the differences in national legislations of the world countries, aggravate the problems in the field of fundamental human rights. The study of international legal regulations for human right to life protection in the context of applying innovative biomedical technologies defines the existence of important and fundamental issues in this sphere, which determines the necessity of their solution based on the international law.*

Problem Statement. *The actual bioethical problems that arise in connection with development of biomedical technologies for human cloning, cryopreservation of cells, tissues, organs, embryos, and human body, human embryonic stem cells, genetic diagnostics, genetic engineering and so on have been considered.*

Purpose. *The purpose of this research is to define the modern threats and challenges to human life in the context of applying the innovative biomedical technologies and their solution based on the international law.*

Materials and Methods. *Based on the dialectical and systematic method, the international legal regulations for innovative application of biomedical technologies in the context to the human right to life have been studied.*

Results. *The analysis of international legal acts and resolutions of the international organizations (the United Nations, the Council of Europe, the European Union) has shown their high effectiveness in terms of solution of the abovementioned problems and further prevention of violations of human right to life, given the development of science and technology.*

Conclusions. *Currently, there is an objective necessity to harmonize the national legislation of different states in the area of human rights and bioethics, as well as to develop general rules of international law of binding character.*

Keywords: international law, human right to life, innovations, and biomedical technologies.

The development of innovative biomedical technologies, in particular in genetics, embryology, cytology, and transplantology, has significantly influenced the preservation and prolongation of human life. At the same time, the biomedical technologies for human cloning, cryopreservation of cells, tissues, organs, and human embryos, production of human embryonic stem cells, genetic diagnostics, genetic engineering, etc., have generated a lot of bioethical problems. The national governments try to regulate these problems at the level of national legislation, but their

solution is possible only based on international cooperation, especially, within the framework of international organizations, namely, the United Nations, the Council of Europe, and the European Union.

Based on the analysis of international documents, it is possible to address the above mentioned problems and to prevent violations of human rights, including the most fundamental right to life, taking into consideration the current level of development of science and technology.

The purpose of this research is to identify modern threats and challenges to human life related to the application of innovative biomedical

technologies and ways of their solution based on international law.

As a result of progress in science and modern technologies, the range of opportunities for managing the human life process from the moment of its birth to biological death has widened. That is why, the human being is often perceived as a biological organism whose value depends on its anatomical, genetic, and other characteristics.

Proceeding from the above, it is important to meet the criteria for life safety of current and future generations, as well as the principle of free and informed consent for practical application of individual technologies relating to human beings. In addition, for the persons who are not able to give consent, Part 1 of Art. 6 of the Convention on Human Rights and Biomedicine of April 4, 1997, known as the Oviedo Convention (hereinafter referred to as "the Oviedo Convention") states that "an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit" [1].

In its resolution 1997/71 "Human Rights and Bioethics" of April 16, 1997 (par. 2), the United Nations Commission on Human Rights "invites governments, the specialized agencies and other organizations of the United Nations system, in particular the United Nations Educational, Scientific and Cultural Organization and the World Health Organization, and other intergovernmental, particularly regional, organizations and non-governmental organizations to inform the Secretary-General of activities being carried out to ensure that the life sciences develop in a manner respectful of human rights and beneficial to humanity as a whole" [2].

In its Recommendation 1468 on biotechnology (2000) of July 29, 2000, the Parliamentary Assembly of the Council of Europe (hereinafter referred to as "PACE") emphasizes the importance of "new technologies in medicine and biology being compatible with fundamental ethical principles, human rights, and human dignity" [3].

Each year, innovative technologies in the field of reproductive medicine, cryopreservation, ge-

netic diagnostics and cloning are getting more and more widespread. Usually, *in vitro* fertilization (IVF)¹ that is an auxiliary function in human reproduction is accompanied by a high embryo mortality rate (due to their natural death and deliberate destruction) as compared with the number of those who have a chance to live. The technology involves the deliberate creation of a larger number of embryos for the purpose of their further selection both at the pre-implantation² (when unnecessary frozen embryos are used for experiments such as biomaterial or are destroyed) and post-implantation stages³ (reduction of "excessive" embryos, i.e. selective abortion).

At the same time, in its resolution on human cloning of September 7, 2000 (par. 7), the European Parliament "renews its call for human artificial insemination techniques that do not produce an excess number of embryos in order to avoid generating superfluous embryos" [4].

The issues related to change of the purpose of human embryos created by this technology, their use for research studies, as well as storage (cryopreservation) and destruction have involved numerous ethical and legal considerations. As a result, the legal status of embryos and human gametes in the context of their destruction (selection and reduction) in the process of application of auxiliary reproductive technologies has been considered at the international law level. The implementation of selection at the prenatal stage of human development borders with eugenics. Therefore, "the prohibition of eugenic practices, in particular those aiming at the selection of persons" has been clearly stated in the context of the right to integrity of the person in Part 2 of Art. 3 of the Charter of Fundamental Rights of the European Union of December 7, 2000 (hereinafter referred to as "the EU Charter") [5].

Often the risk of transmission of hereditary diseases is a reason for *in vitro* fertilization in or-

¹ *Ex vivo* ovum fertilization (*in vitro* is Latin term literally meaning "in the glass").

² Before implantation in mother organism.

³ After implantation in mother organism.

der to select an embryo at the pre-implantation stage. For this, pre-implantation genetic diagnostics is used, which is carried out on the 5th day of the embryo development by studying its DNA to detect possible defects of development (chromosomal pathologies, genetic disorders, and anomalies), as well as to select the "desired" embryo among the cultivated ones before its implantation in the woman's body.

The negative consequence of this diagnosis is the reduction of superfluous embryos by sex or based on genetic characteristics. Thus, Article 14 of the Oviedo Convention states, "the use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided", and Article 18 says that, that "The creation of human embryos for research purposes is prohibited" [1].

The Universal Declaration on the Human Genome and Human Rights adopted at the 29th session of the General Conference of UNESCO on November 11, 1997, states, "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity" (Art. 6) [6].

At the moment, the use of "asexual reproduction" biotechnology i.e. cloning continues to attract attention of international community. This technology has become the subject of consideration by scientists from different fields, including biology, medicine, genetics, jurisprudence, philosophy, etc.

The cloning technology is carried out *in vitro* by transferring a somatic cell⁴ nucleus into egg cell from which its own nucleus has been removed, with its subsequent implantation into the mother's body (*in utero*⁵), in the case of reproductive cloning, or without the intention of further implantation, in the case of therapeutic cloning.

⁴ Any cell of living organism other than the reproductive cells, therefore such reproduction is considered asexual reproduction.

⁵ *In utero* is Latin term literally meaning "in the womb".

The international community is aware of the objective need to prohibit the human reproductive cloning. At the same time, the issue of human therapeutic cloning depends on the national policy of the states regarding the protection of human life at the embryonic stage of development. Certainly, the therapeutic cloning is a significant step for the further development of regenerative medicine in terms of the use of stem cells for treating diseases. However, the production of embryonic stem cells by cloning for research and therapeutic use gives rise to the ethical problem of human rights to life and respect for human dignity. In particular, due to the fact that person is perceived as an object for research and a source of stem cells rather than their donor.

The Universal Declaration on the Human Genome and Human Rights proclaims, "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" [6].

Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings of January 12, 1998 says, "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited" (Art. 1) [7].

Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions contains a list of exclusions from patentability based on public order or morality, including the processes for modifying the germ line genetic identity of human beings and processes for cloning human beings, as well as the use of human embryos for industrial and commercial purposes [8].

The Fifth Framework program of the European Community for research, technological development and demonstration activities (1998–

2002) [9] and Council Decision 1999/167/EC of January 25, 1999, on adopting a specific program for research, technological development, and demonstration on quality of life and management of living resources (1998–2002) [10] proclaim, "no research activity understood in the sense of the term "cloning", with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo, will be supported."

In the aforementioned Resolution on human cloning, the European Parliament considers, "therapeutic cloning which involves the creation of human embryos solely for research purposes, poses a profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to public policy as adopted by the European Union" (par. 2), urges "maximum political, legislative, scientific, and economic efforts to be aimed at therapies that use stem cells taken from adult subjects" (par. 5), and mentions "there are other ways than embryonic cloning of curing serious illnesses, such as those that involve taking stem cells from adults or from the umbilical cords of new-born babies" (p. c) [4].

The EU Charter defines "the prohibition on making the human body and its parts as such a source of financial gain" and "the prohibition of reproductive cloning of human beings" (Art. 3) [5].

Resolution 1352 (2003) of the Parliamentary Assembly on the Human Stem Cell Research of October 2, 2003, states, "Human stem cells may be derived from a growing number of tissues and fluids from humans of any age and are not limited to embryonic sources" (par. 3), "The harvesting of embryonic stem cells for the time being necessitates the destruction of human embryos" (par. 5), and "The destruction of human beings for research purposes is against the right to life of all humans and against the moral ban on any instrumentalization of humans" (par. 10) [11].

The General Assembly in United Nations Declaration on Human Cloning of March 8, 2005, calls on Member States "to prohibit all forms of

human cloning inasmuch as they are incompatible with human dignity and the protection of human life; "(par. b), as well as "to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity" (p. c) [12].

Regulation (EU) No 1291/2013 of the European Parliament and of the Council of December 11, 2013, on the establishment of the *Horizon 2020* Program – the Framework Program for Research and Innovation (2014–2020) and repealing Decision No. 1982/2006/EC in the provision on ethical principles states that "research activity aiming at human cloning for reproductive purposes" should not be financed" (par. 3 of Art. 19) [13].

The development of genetics (in particular, human genomics, especially in the field of modification of human genes) and genetic engineering aiming at experiments on the creation of chimeras using human genes⁶ (using the biotechnological method that enables the transfer of selected individual genes from one organism to another) and transgenic (genetically modified) organisms⁷ has caused a new wave of threats to human identity.

Article 13 of the Oviedo Convention on Interventions in the Human Genome 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" [1].

The UN Human Rights Commission resolution 1997/71 on Human Rights and Bioethics of April 16, 1997, "draws the attention of Governments both to the importance of research on the human genome and its applications for the improvement of the health of individuals and mankind as a whole and to the need to safeguard the rights of the individual and his dignity, as well as his identity and unity" (par. 4) [2].

⁶ Chimeric (interspecies) cloning (for instance, in Great Britain).

⁷ Firstly, the human embryo.

The International Declaration on Human Genetic Data as adopted by the UNESCO General Conference resolution of October 16, 2003, outlines the content of human identity (Art. 3), proclaims the special status of human genetic data (Art. 4), non-discrimination (Art. 7), and defines the peculiarities of the collection, processing, use, and storage of genetic data and other important provisions necessary for the protection of human rights and dignity [14].

At the same time, the PACE in its Biotechnology Recommendation 1468 (2000) of June 29, 2000, states that biotechnologies for manipulating or changing genes "have also resulted in serious public concerns about the safety and ethical acceptability of some of the new inventions" (par. 1) [15].

While the EU Charter forbids "eugenic practices, in particular, those aiming at the selection of persons", modern technologies open up possibilities for artificial selection of the necessary genes – genetic reprogramming (genetic modification) of person, which enable improving the physical, intellectual, and other abilities. However, the ultimate consequences of the use of such genetic technologies for the human life and health and for the future generations have not been comprehensively studied.

The human genome was decrypted within the framework of a large-scale international scientific research project *Human Genome* (1990–2003) [16]. To this end, the Council of Europe created a body whose tasks were to monitor the development of research process of this project in order to secure respect for ethical principles in the context of human genome research, to assess the impact of such research on health risks, and to carefully examine all ethical aspects of the project. It should be noted that the Steering Committee on Bioethics plays an important role in these matters.

In Recommendation 1512 (2001) on protection of the human genome by the Council of Europe of April 25, 2001, the Parliamentary Assembly notes that given the enormous ethical and

economic implications of the project, its guiding principle should be the protection of human dignity, and recommends the Committee of Ministers "to invite every Council of Europe member state concerned to set up, under its own domestic legislation, a national authority having the express task of monitoring, informing and advising on the compliance of research on the human genome with universally recognized ethical and moral principles of respect for life and human dignity" [17].

The General Declaration on Bioethics and Human Rights adopted by the General Conference of UNESCO on October 19, 2005, states that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms, in order to protect and to realize the interests of future generations "it is necessary to take into account the impact of life sciences on future generations, including on their genetic constitution" (par. 16) [18].

The fundamental role of cryotechnologies in preserving the viability of organisms and organs (tissues, cells) of a person should be noted as well. As the sphere of artificial reproduction develops, the technology for cryopreservation of human embryos is getting widespread. It is based on deep low-temperature⁸ freezing of embryos in liquid nitrogen, with the preservation of their further viability. The most effective and safest method for freezing is vitrification. However, the preservation of "reserve" embryos for their possible further use (mainly, for in utero implantation) raises the ethical and legal problem of the destruction of cryopreserved human embryos not only as a result of their selection, but also because of the expiration of their storage as determined in accordance with national legislation (or contract) despite their physical viability after the expiration of this term.

⁸ At a temperature down to -196°C .

In addition, the issue of subsequent fate of non-implanted human embryos in the context of their donation for biomedical research becomes the subject of litigations in the European Court of Human Rights. Thus, in the Case of Parillo v. Italy [19], the triable issue was the applicant's desire to donate non-implanted cryopreserved embryos for research after the death of her husband, which was prohibited by Italian law. In the applicant's opinion, it was violation of the right to respect for private life and the right to peaceful possession of her property as defined in Article 8⁹ of the Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 [20] and Art. 1¹⁰ of Protocol No. 1 to the mentioned Convention of 1952 [21]. The court resolved that human embryos cannot be considered in the context of the concept of property, and therefore established that the claim should be denied as inadmissible. On August 27, 2015, the court decided there was no violation of Art. 8 by the state¹¹ at the national level with respect to the applicant.

The Oviedo Convention prohibits "the creation of human embryos for research purposes" (Part 2 of Art. 18) [1]. At the same time, the issue of donation and posthumous reproduction (after the death of one of the spouses) has given rise to numerous problems.

An increase in the number of experiments in the field of cryonics (posthumous and life-time cryopreservation of the body) based on the body hypothermia with simultaneous saturation of cells with cryoprotectors in order to prevent the formation of ice crystals during the body freezing (perfusion) also has aroused interest among researchers. The purpose of research in this area is to restore the viability of human being after defrosting. At present, the life-time cryopreservation of person is treated as murder (or euthanasia in the form of assisted suicide). However, researchers see the possibility of its use in the fu-

ture, as technical capabilities grow, provided the human safety requirements are met, to address the problems of "incurable" diseases, lack of organs for transplantation, etc.

The international conference on the occasion of the 20th Anniversary of the Oviedo Convention, which took place in Strasbourg, France, on October 24–25, 2017, became an important platform for discussing the modern bioethical issues related to human rights by the international community [22]. The main subject of discussion is the human being and perception of human being as a biomaterial in terms of transformation of human organs, tissues or cells, which generates a number of problematic ethical issues that have received a public response in the context of protecting human rights and dignity through the prism of bioethics and international law.

The problem of protecting human rights and human dignity in the context of application of modern biotechnologies and their moral legitimacy has led to the objective necessity of forming a new line of international law – the protection of human rights in the context of bioethics. Numerous problems related to the human right to life, which arise from the threats posed by advanced innovative biomedical technologies, require legal regulation at the international level, primarily, within the framework of the United Nations. "Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences" (par. *a*) of the UN Declaration on Human Cloning) [12].

States are trying to resolve bioethical issues at the national level, but the norms of their legislation are often different, which, in terms of life internationalization, is a problem to be solved based on international law.

The difference in national legislations on bioethical issues leads to the development of "tourism" in the biomedical field, which allows citizens to get around national law in order to obtain the biomedical services they need in other countries (in the field of artificial reproduction, transplantation, euthanasia, etc.). Each year, the number of

⁹ Right to respect for private and family life.

¹⁰ Protection of property.

¹¹ Italy.

consumers of these services increases. Ukraine, Russia, and Belarus have been currently increasing the export of biomedical services due to their affordability, and legal access to them.

Consequently, the prohibition on the national level of certain biomedical practices in one country does not solve the pressing problems of society, if the same practices can be legally implemented in other countries. Therefore, there is a need to harmonize the laws of different states in this area and to develop general rules of the international law, which must be binding upon all states.

When implementing the results of R&D progress, it is necessary to compare the goals and means to determine their benefits to human being, the balance of scientific interests and funda-

mental human rights, their moral admissibility and safety for the life and existence of future generations. The development of innovation in science and technology should aim at protecting and improving the human life. Doing so, the principle of human priority must be respected, "The interests and welfare of the human being shall prevail over the sole interest of society or science" (Art. 2 of the Oviedo Convention [1], Art. 3 of Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research [23]).

It is important to remember that innovative biotechnology is a powerful weapon and therefore its use in the third millennium should be solely for the benefit of individual, which must be guaranteed by universal international law.

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МІЖНАРОДНО-ПРАВОВІ АСПЕКТИ ЗАХИСТУ ЖИТТЯ ЛЮДИНИ У ПРОЦЕСІ ЗАСТОСУВАННЯ ІННОВАЦІЙНИХ БІОМЕДИЧНИХ ТЕХНОЛОГІЙ

Вступ. Розвиток інноваційних біомедичних технологій та поширення біомедичних послуг, а також відмінності національних законодавств країн світу загострюють проблеми у галузі фундаментальних прав людини. Дослідження міжнародно-правового регулювання захисту права людини на життя у процесі застосування інноваційних біомедичних технологій визначає наявність важливих та принципових питань у цій сфері, що зумовлює необхідність їх вирішення на основі міжнародного права.

Проблематика. Біоетичні проблеми, що виникають у зв'язку з розвитком біомедичних технологій клонування людини, кріоконсервації клітин, тканин, органів та ембріонів людини, отримання ембріональних стовбурових клітин людини, генетичної діагностики, генної інженерії тощо на сьогодні є досить актуальними та дискусійними.

Мета. Визначення сучасних загроз і викликів життю людини у процесі застосування інноваційних біомедичних технологій та вирішення їх на основі міжнародного права.

Матеріальні методи. На основі діалектичного та системного методу досліджено міжнародно-правове регулювання застосування інноваційних біомедичних технологій та їх співвідношення з правом людини на життя.

Результати. Аналіз міжнародно-правових актів і резолюцій міжнародних організацій (Організації Об'єднаних Націй, Ради Європи, Європейського Союзу) свідчить про достатньо високу їх ефективність у подоланні вищезазначених проблем та подальшого запобігання порушень щодо права людини на життя з урахуванням розвитку науки та техніки.

Висновки. Наразі існує об'єктивна необхідність уніфікації законодавств різних держав у сфері прав людини й біоетики, а також вироблення загальних норм міжнародного права зобов'язального характеру.

Ключові слова: міжнародне право, право людини на життя, інновації, біомедичні технології.

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МЕЖДУНАРОДНО-ПРАВОВЫЕ АСПЕКТЫ ЗАЩИТЫ ЖИЗНИ ЧЕЛОВЕКА В ПРОЦЕССЕ ПРИМЕНЕНИЯ ИННОВАЦИОННЫХ БИМЕДИЦИНСКИХ ТЕХНОЛОГИЙ

Введение. Развитие инновационных биомедицинских технологий и распространения биомедицинских услуг, а также различия национальных законодательств стран мира обостряют проблемы в области фундаментальных прав человека. Исследование международно-правового регулирования защиты права человека на жизнь в процессе применения инновационных биомедицинских технологий определяет наличие важных и принципиальных вопросов в этой сфере, что обуславливает необходимость их решения на основании международного права.

Проблематика. Биоэтические проблемы, возникающие в связи с развитием биомедицинских технологий клонирования человека, криоконсервации клеток, тканей, органов и эмбрионов человека, получения эмбриональных стволовых клеток человека, генетической диагностики, геной инженерии и прочее на сегодня достаточно актуальные и дискуссионные.

Цель. Определение современных угроз и вызовов жизни человека в процессе применения инновационных биомедицинских технологий и решения их на основании международного права.

Материалы и методы. На основании диалектического и системного метода исследовано международно-правовое регулирование применения инновационных биомедицинских технологий и их соотношение с правом человека на жизнь.

Результаты. Анализ международно-правовых актов и резолюций международных организаций (Организации Объединённых Наций, Совета Европы, Европейского Союза) свидетельствует о достаточно высокой их эффективности в преодолении вышеуказанных проблем и дальнейшего предотвращения нарушений относительно права человека на жизнь с учетом развития науки и техники.

Выводы. Сейчас существует объективная необходимость унификации законодательств разных государств в сфере прав человека и биоэтики, а также выработки общих норм международного права обязывающего характера.

Ключевые слова: международное право, право человека на жизнь, инновации, биомедицинские технологии.