

Halyna Tereshkevych (s. Diogena)¹

Danylo Halytsky²

Problems of Consistency of Regulatory and Legal Acts on Regulation of the Health Care System of Ukraine with the Principles of Bioethics

1. Introduction

The demographic crisis in Ukraine is prompting public authorities to reflect on the problem of the value and dignity of human life. The situation in Ukraine is characterized by low birth rates, high overall and infant mortality, short active life expectancy, widespread childlessness, high stillbirths, declining populations, and especially abortions, which make Ukraine one of the world's leading countries.

Many definitions used in Ukrainian legislation are very contingent, imperfect, and contradictory from the point of view of bioethics.

The lack of consistency of norms on the beginning of human life in the legislation creates a pluralism of interpretations, which is a significant shortcoming in the entire legal field, as this point is the acquisition of an inherent human right to life.

The human person is realized in his/her integrity, reasonableness, freedom and responsibility, ethics, and a basic right to life. The officials

¹ PhD in Public Administration, Associate Professor at the Department of Philosophy and Economy.

² Lviv National Medical University, Doctoral Candidate at the Department of Parliamentarism and Political Management, National Academy for Public Administration under the President of Ukraine, bioethiics.ua@gmail.com, <https://orcid.org/0000-0003-4427-7872>.

at different levels are first of all meant to take care of health, life, and respect for the dignity of the citizens of Ukraine, and to serve the community. Actions that contradict the norms of bioethics, including the promotion of euthanasia, social and other types of abortion, advertising of drug substitutes, contraception, artificial insemination, some aspects of genetic engineering, etc., should not be allowed.

From the point of view of state formation, the consistency of the current legislative acts in the field of health care with the principles of bioethics will make it possible to strengthen society spiritually and morally. Therefore, all citizens in the state will respect the dignity, integrity, and inviolability of human life.

In recent years, the study of the consistency of regulatory and legal acts on the regulation of the health care system with the principles of bioethics has received attention from both the scientific community and practitioners. Among the Ukrainian researchers who studied this problem, we should mention: M. Bilynska, V. Goshovska, P. Vorona, L. Danylenko, N. Nazar, L. Pashko, P. Shevchuk, and others, and among foreign scientists, F. D'Agostino, N. Blazques, E. Zgrecha, M. Casini, H. Kelsen, S. Cotta, D. Ross, and others. However, the issues of legal reform of the health care system based on the values and principles of bioethics, unfortunately, have remained out of the attention of the scientific community. The proposed article is an attempt to close this gap in the study of problems of attitude to human life at all stages of its existence and manifestations.

The *purpose* of this publication is a scientific and theoretical justification of the need for consistency of regulations governing the health care system of Ukraine with the principles of bioethics, which will serve the interests of a human being, his/her dignity and unique value, as well as ensure quality and sustainable changes in the state and society.

The accomplishment of the purpose means coping with the following tasks: to define a level the subject has been researched by domestic and foreign scientists; to characterize the regulatory support of state regulation of health care reform on the basis of bioethics; to emphasize the attention of public officials in the field of health care on the dignity and inviolability of human life as fundamental values of Ukrainian state formation; to highlight the specific features of bioethical problems in Ukrainian society

in the field of ensuring the right to fetal life; to identify the influence of international health organizations on the formation of legislation in Ukraine.

Research methodology. A set of interrelated scientific methods have been used to achieve the goals and objectives of scientific research, namely:

- method of analysis and synthesis – to determine the content, principles of bioethics as a basis for regulatory reform of the health care system;
- modeling method – to develop and substantiate the model of legislative regulation of health care reform on the basis of bioethics;
- prediction method of the obtained results – to determine the priority areas for improving the legislative regulation of health care reform on the basis of bioethics and the formulation of relevant scientific and practical recommendations to public authorities.

The study is based on the analysis of regulations, strategic documents and programs, foreign and domestic scientific sources, and more.

The logic of the presentation of the studied material. The scientific and theoretical substantiation of legislative regulation of health care reform in Ukraine on the basis of bioethics will contribute to: strengthening the efficiency and effectiveness of public administration of the health care system, intensification of work of public authorities and the formation of effective approaches to practical management, strengthening their responsibility for bioethical consequences of their professional activity in order to protect the person, his/her human dignity, safety, health, and life of citizens in general and each person in particular; initiating and conducting large-scale educational work among adolescents, youth on sexual culture, responsible motherhood/fatherhood; improving the quality of professional training of medical professionals in terms of readiness for such preventive/educational work; development of the state program of development of the health care system on the basis of bioethics; development of relevant domestic legislation.

2. Problems of consistency of legal norms with the principles of bioethics

The fundamental values of a person must be protected not only morally but also legally: they are human values on which international tribunals

and national constitutions must take a stand. Here emerges a problem between ethics and law, between moral and civil law³.

The age-old philosophical debate about the relationship between civil law and moral law is an important challenge for a democratic society today.

St. Thomas Aquinas emphasized back then that the whole sphere of morality cannot be enveloped by law. However, the law cannot justify morality, it can recognize its requirements at best. Therefore, one should not strive for an ethical state that would decide what is good and what is evil. Nevertheless, the fundamental values necessary to guarantee the common good must also be protected by law. Therefore, if the law does not protect the good necessary for the coexistence of people and the common good (as, say, laws allowing abortion), this law is not a law, and, therefore, it is possible to refuse to comply with it as the conscience dictates, and the law has to change.

The fundamental right to life of a single living creature, which has already been born or is about to be born, a family, the necessary medical care are the basic ethical attributes because they serve to protect the common good. This is not “an ethical minimum”, because it is not about trifles, but about the common good, which must be protected in the general interest.

In today’s pluralistic society, for a number of reasons, and especially due to the emergence of bioethical thinking and the problems it poses in the field of law, the need to clarify the axiological foundations of the law becomes increasingly clear in order to make human rights more inherent, those rights, which are sanctioned by law, must guide human behavior in the case of moral choice, which involves the sciences about life and health.

In the dominant culture, the truth-freedom binomial expansion paradoxically hinders the effective protection of human life by state structures and promotes the emergence of subtle forms of tyranny, in which a handful of people can decide the fate of many others.

It has been a long time since abortion laws in force in many Western countries have essentially transformed the notion of “crime” into

³ F. D’Agostino (1993), *Bioetica e diritto / Medicina e Morale*. Roma: UCSC Facoltà di Medicina e Chirurgia A. Gemelli, N° 4, Italy, p. 675–691.

“a right” that legitimizes the abuse of power by the stronger in relation to the life of the weaker and innocent⁴.

This confusing legal situation, in which the value of human life rises and falls on the scale of values, as if some subjective interest, is a consequence of ethical relativism and legal positivism, which turned the theory of distinction between law and morality into a theory of radical separation of these two concepts⁵.

In modern legal debates, one can often hear about the immorality of law. Ultimately, this view leads to the concept of law, which cuts off any criterion of justice and the common good⁶.

Increasingly more authors are proposing theories of the ethical minimum that leave room for morality, but only to the extent that morality recognizes the absolute primacy of law and is based on models of legal principles recognized and sanctioned by international declarations of human rights. Where this is not the case, morality is limited to the imagination of individuals, without any legal “provision” at the collective level⁷.

According to this doctrine, the law should not depend on the truth, but rather on the act of normative will of those in power (legal positivism)⁸.

The consequences of such guidelines have a significant impact on both the legal and political systems. Indeed, on the one hand, the law throws out its own ethical content, and instead of leading to the search for truth to the common good, it comes down to a simple procedural mechanism for seeking consent. On the other hand, a democratic system, which should ideally be an effective “mechanism” for protecting the rights of every individual at any stage and under any conditions of

⁴ Giovanni Paolo II (1995), *Lettera Enciclica Evangelium Vitae*, 25 marzo 1995, Libreria Editrice Vaticana, Città del Vaticano, Vatican, no. 11.

⁵ D. Ross (2002), *The right and the good*. Press Oxford University, Oxford, England, p. 30

⁶ H. Kelsen, M. Losano (1966), *La dottrina pura del diritto*. Giulio Einaudi Editore, Torino, Italy, p. 32.

⁷ F. D'Agostino (1991) *L'approccio morale al diritto / Scritti in onore di Angelo Falzea*. Milano: Giuffrè, 1991. V. I, Italy, p. 230.

⁸ H. Kelsen, M. Losano (1966), *La dottrina pura del diritto*. Giulio Einaudi Editore, Torino, Italy, p. 33.

its existence, becomes a “goal” that serves to preserve the interests of the majority.

In fact, the modern concept of democracy should be characterized not so much by its formal mechanisms, which was inherent in the model of democracy of the last century, but special respect for individual rights and protection of human dignity⁹. Such a democracy can be called a state governed by the rule of law, in which the ruling power itself is limited by laws aimed at protecting the individual, sanctioned by the basic principles of the constitution, which cannot be manipulated even by the majority in power.

True democracy is substantial¹⁰, and its value increases or decreases along with the values it embodies and develops. Fundamental and inalienable values, in this case, are the dignity of each person, respect for his/her inalienable and undiminishable rights, and the recognition of the common good as the goal and regulatory criterion of political life. Therefore, the development of society and a healthy democracy requires a new understanding of human and moral values, existential and natural ones arising from the very life of the human being and expressing and protecting the dignity of the human person – values that no individual, no majority, and no state can neither create nor change or destroy, but only acknowledge, respect, and develop.

For a long time in the legal world, there is a need to explain the ethical and axiological aspect of law and to study not so much its sources as its foundations by returning to those objective and universal values that normatively support it and are based on the ontological structure of human as a person¹¹.

Thus, the constitutions are designed to protect the fundamental rights of the individual, which are necessary to ensure the orderly coexistence of citizens and for the very possibility of the existence of their social life. Therefore, such a constitutional minimum must be enshrined

⁹ N. Blazques (1996), *Bioética fundamental*. Biblioteca de Autores Cristianos, Madrid, Spain, p. 46.

¹⁰ F. D'Agostino (1993), *Bioetica e diritto / Medicina e Morale*. Roma: UCSC Facoltà di Medicina e Chirurgia A. Gemelli, N° 4, Italy, p. 406.

¹¹ S. Cotta (1991), *Il diritto nellesistenza. Linee di ontofenomenologia giuridica* / [2 ed.]. Giuffrè, Milano, Italy, p. 194.

in the constitution of each state, because it is a necessary element of the very existence of any human society.

Therefore, the legislator is required not to re-create, but rather to comprehend the needs of a person living in society, in search of not so much consent as the objective moral law, which “is inscribed in the heart of every person and is the normative starting point of civil law”. Only based on such preconditions, the law can regain its true function, protected from the dangers of ethical relativism, which throughout history has often served to justify the arbitrariness of political authorities and combined justice and freedom with authoritarianism and abuse, especially towards the weakest. The encyclical “*Evangelium Vitae*” (“Gospel of Life”) of Pope John Paul II openly calls on legislators to respect the “truth of law” and urges them to say a courageous “no” to any violence against human life and any arbitrariness against it¹².

3. Shortcomings of the legislation of Ukraine on the protection of human dignity and a basic right to life

Bioethics draws attention, in particular, to the biological and anthropological status of the human embryo, which has all the characteristics of the human personality from the moment of fertilization: driven by the personal genome, its own project-program of life and human dignity that deserves respect. From the moment of fertilization, a living human embryo is a human subject with a well-defined identity, which begins its own, continuous, constant, and coordinated development from that moment; has the right to his/her own life, and any intervention not in favor of the embryo is considered as an act that violates this right¹³. Bioethics states that every human life is inviolable from the moment of fertilization to natural death (God-ordained departure).

As noted by Natalia Nazar, the Civil Code of Ukraine (dated Jan 16, 2003 No.435-IV) in Part 2 of Art. 25 determines the civil capacity of an individual from birth, which is already contrary to the principles of bio-

¹² Giovanni Paolo II (1995), *Lettera Enciclica Evangelium Vitae*, 25 marzo 1995, Libreria Editrice Vaticana, Città del Vaticano, Vatican, no. 70.

¹³ H.T. Tereshkevych (2018), *Osnovy bioetyky ta biobezpeky* [Fundamentals of bioethics and biosafety]. Ternopil: Press TDMU (in Ukrainian).

ethics. Such a definition of the child in the legislation in Art. 281 P. 6 of the same code entails permission for artificial termination of pregnancy (abortion)¹⁴.

According to this Code, a person has the legal status of a child until he or she reaches legal adulthood. A child is considered a minor until he or she reaches the age of fourteen (Art. 31, Part 1). The Code does not specify the lower limit of childhood¹⁵.

According to Art. 115 of the Criminal Code of Ukraine (dated Apr 05, 2001, No.2341-III) "pregnancy, regardless of its term, is an aggravating circumstance for the murder of a woman"¹⁶. However, when it comes to abortion, the right of a conceived child to live is neglected. That is, we have a precedent, in which the murder of a child in the womb is an aggravating circumstance in sentencing in one case; in another case, we use the same murder, but calling it a method of family planning, without any punishment or responsibility.

The only way to overcome the existing contradictions is to bring these laws in accordance not only with the Constitution but also, above all, with the natural right of every person to life, regardless of the stages or manifestations of his/her existence. Ukraine needs to conform regulations related to the protection of human life and health with the principles and values of bioethics.

Legislation of Ukraine in the field of health care according to Art. 9 of the Basic Law of Ukraine is adapted to the relevant international documents if the Verkhovna Rada agrees¹⁷. The legislation of Ukraine implements the main documents of international organizations on compliance with the norms and principles of bioethics in the practice of health care. The basis of such regulations should be the statutory right of a person

¹⁴ N.O. Nazar (2009), On the need to amend the legislation of Ukraine in the field of health care as a mechanism of demographic policy. Proceedings of the Democratic Governance in the Context of Global Challenges and Crises (Ukraine, Lviv, 2-3 April). Lviv: Press LRIDU NADU, pp. 519-522.

¹⁵ VRU (2003), "Civil Code of Ukraine", Lists of the Verkhovna rada of Ukraine, vol. 40-44, Art. 356.

¹⁶ VRU (2001), "Criminal Code of Ukraine", Lists of the Verkhovna Rada of Ukraine, vol. 25-26. Art. 131.

¹⁷ VRU (1996), "Constitution of Ukraine", Retrieved from: <http://zakon5.rada.gov.ua/laws/show/en/254%D0%BA/96-%D0%B2%D1%80> (accessed 3.01.2020).

to life and respect for his dignity from the moment of fertilization to natural death.

A logical addition to the European Convention on Human Rights (1950)¹⁸ and the European Social Charter (1961, amended in 1996)¹⁹ is the European Convention for “the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine”(1997)²⁰, which was signed by Ukraine together with 35 states, of which 28 states have ratified it. However, Ukraine has not ratified this convention. This means that legislation on life and health must be drafted in accordance with the requirements of the latest Convention, based on the principles of bioethics.

The Universal Declaration on Bioethics and Human Rights, adopted by UNESCO (2005)²¹, officially recognized bioethics at the level of the international organization as a global field of knowledge that needs legal support and priority attention from legislators around the world. In fact, the Universal Declaration on Bioethics and Human Rights has become the first universal source of international bioethical law, outlining the fundamental principles of bioethics and emphasizing the international global nature of bioethical issues.

The legislation of Ukraine on health care should be based on the Constitution of Ukraine, where one of the main principles is to ensure the priority of universal values (Art. 3)²².

From the standpoint of bioethics, research on humans is lawful to be conducted for the progress of medicine in various fields while adhering

¹⁸ European Convention for the Protection of Human Rights and Fundamental Freedoms 4.XI.1950. Rym, Italy. Retrieved from: www.hri.org/docs/ECHR50.html. (accessed 3.01.2020).

¹⁹ European Social Charter, 1961, revised by the Council of Europe. Strasbourg, May 3, 1996 Retrieved from: www.coe.int/T/E/Human_Rights/Esc/ (accessed 3.01.2020).

²⁰ Convention on the Protection of Human Rights and Dignity in the Application of Biology and Medicine, 1997 CE. Retrieved from: conventions.coe.int/Treaty/EN/Treaties/Html/164.htm (accessed 3.01.2020).

²¹ UNESCO Universal Declaration of Bioethics and Human Rights, 19 October 2005. Retrieved from: <http://unesdoc.unesco.org/images/0014/001461/146180r.pdf>. (accessed 3.01.2020).

²² VRU (1996) “Constitution of Ukraine”, available at: <http://zakon5.rada.gov.ua/laws/show/en/254%D0%BA/96-%D0%B2%D1%80> (Accessed 3.01.2020).

to ethical norms²³. According to the Law on health care, “biomedical research is allowed to be used in medical practice for socially useful purposes, provided that they are scientifically substantiated, the benefit of the expected success outweighs the risk of causing life-threatening consequences. Experiments are forbidden to be conducted on patients, prisoners, prisoners of war, as well as a therapeutic experiment on people whose disease is not directly related to the purpose of the experiment” (Art. 45)²⁴. Recommendation of the Parliamentary Assembly of the Council of Europe No.1046/1986 states that human embryos and fetuses are also inherently human, so they should be treated with due respect and any interference with their bodies, even if they are not viable, should be prohibited (experiments, taking organs for transplantation etc.) (§10)²⁵. The legislatures in each country have to ensure it.

Ukraine has a critical demographic situation, the consequences of which threaten the future of the state, as the birth rate does not ensure the natural reproduction of the population. In Ukraine, the law allows artificial “termination of pregnancy” (abortion), which is morally unacceptable. Operations of artificial termination of pregnancy are performed in accredited health care facilities during pregnancy not more than 12 weeks long at the request of the woman (according to the legislation

²³ VRU (2000) Order of the Ministry of Health of Ukraine: “On approval of the Instruction for medicinal products and examination of clinical trial materials and the standard provision on the ethics committee”, No. 281 – has lapsed. VRU (2006), Order of the Ministry of Health of Ukraine: “On Approval of the Procedure for Clinical Trials of Medicines and Expertise of Materials of Clinical Trials and Model Regulations on the Ethics Commission” No.66 – became invalid on the basis of: VRU (2009), On approval of the Procedure for conducting clinical trials of medicinal products and examination of clinical trial materials and Model Regulations on Ethics Commissions: Order of the Ministry of Health of Ukraine No. 690 of 23.09.2009 Retrieved from: <http://zakon.rada.gov.ua/laws/show/z1010-09> (accessed 3.01.2020).

²⁴ VRU (1992), Fundamentals of the legislation of Ukraine on health care: Law of Ukraine of 19.11.1992 № 2802-XII. *Information of the Verkhovna Rada of Ukraine*, no. 4. Art. 19.

²⁵ Raccomandazione dell'assemblea parlamentare del consiglio d'Europa. Approvata nella 18^a seduta della 38^a sessione ordinaria. Recommendation 1046 (1986) relative à l'utilisation d'embryons et foetus humains à des fins diagnostiques, thérapeutiques, scientifiques, industrielles et commerciales. Annunziata il 10 marzo 1986. Retrieved from: http://legislature.camera.it/_dati/leg09/lavori/stampati/pdf/012_192001.pdf (Accessed 3.01.2020), Italy.

of Ukraine on health care (Art. 50)²⁶ and the Civil Code of Ukraine (Art. 281)²⁷. Artificial “termination of pregnancy” from 12 to 22 weeks is possible only if the pregnant woman has the relevant indications (according to the Law No. 997-V of Apr 27, 2007)²⁸. According to the law, abortion can be performed to save a woman’s life, preserve her physical and mental health, terminate pregnancy in case of rape or incest, due to fetal malformations, and at the woman’s own request. The Criminal Code of Ukraine (Art. 134) provides for punishment only for illegal abortion by a doctor; an abortion by a person without special medical education; illegal abortion resulting in long-lasting ill health or death. Forcing a woman to have an abortion, resulting in it being performed, leads to criminal liability²⁹. From the standpoint of bioethics, abortion is morally unacceptable. Everyone carries the “image of God” from the moment of fertilization, so abortion is an attack on God himself. No argument can lead to the destruction of the lives of innocent creatures, because the price of human life far exceeds all other values. The law should serve man, not destroy innocent human life. Therefore, it is necessary to change it, taking into account the principles of bioethics. It is necessary to cultivate responsibility and respect for life from school years, to promote the principles of bioethics.

The real danger to human life are methods of artificial insemination³⁰,

²⁶ VRU (1992), Fundamentals of the legislation of Ukraine on health care: Law of Ukraine of 19.11.1992, № 2802-XII. *Information of the Verkhovna Rada of Ukraine*, no. 4. Art. 19.

²⁷ VRU (2003), “Civil Code of Ukraine”. *Lists of the Verkhovna rada of Ukraine*, vol. 40–44, Art. 356.

²⁸ VRU (2007), Law of Ukraine «On Amendments and Repeal of Certain Legislative Acts of Ukraine in Connection with the Adoption of the Civil Code of Ukraine» № 997-V of April 27, 2007. Retrieved from: <https://zakon.rada.gov.ua/laws/show/997-16> (Accessed 4.01.2020).

²⁹ VRU (2001), “Criminal Code of Ukraine”. *Lists of the Verkhovna Rada of Ukraine*, vol. 25–26. Art. 131.

³⁰ VRU (1997), Order of the Ministry of Health of Ukraine: “On approval of the conditions and procedure for the use of artificial insemination and implantation of the embryo (embryos) and methods of their carrying out” No. 24 of 4.02.1997 – has expired on the basis of: VRU (2008), On approval of the Instruction on the procedure for the use of assisted reproductive technologies: Order of the Ministry of Health of Ukraine dated 7.12.2008, No. 771. Retrieved from: <http://zakon.rada.gov.ua/laws/show/z0263->

which contradict the dignity of embryos, lead to their mass destruction, open the way to the crossing of human and animal gametes, cloning, parthenogenesis, which deserve condemnation³¹. The Law of Ukraine on health care allows artificial insemination and implantation of an embryo with the written consent of the spouses while maintaining the anonymity of the donor and medical secrecy (Art. 48)³², which is ethically unacceptable. The recognition of human status as an embryo is a matter of human self-understanding, of responsibility to those who are born, of human rights to equality and non-discrimination.

A countermeasure of assisted reproductive technologies is NaProTechnologies based on establishing the causes of infertility and correcting disorders of natural processes that cause infertility in men and women, and are aimed at conceiving and carrying a child, which provides modern medical and surgical treatment. The criterion of bioethical permissibility of human NaProTechnologies is a marital act with uniting and reproductive functions at the same time; fertilization in a living organism and the auxiliary function of technology. The treatment of female infertility is based on the Creighton model – a popular method in the United States to monitor the cycle of female fertility, which enables to objectively assess hormonal changes during the cycle³³.

NaProTechnology is an ethical way to overcome the problem of infertility. Also, these methods are more efficient and less costly compared to assisted reproductive technologies, and they should gain adequate information support in Ukraine. This should be taken care of by public officials³⁴.

09 – expired on the basis of: VRU (2008), On Approval of the Procedure for the Use of Assistive Reproductive Technologies in Ukraine: Order of the Ministry of Health of Ukraine of 9.09.2013, No. 787. Retrieved from: <http://zakon.rada.gov.ua/laws/show/z1697-13> (accessed 3.01.2020).

³¹ Charter of Healthcare Workers (2010) *Pontifical Council for Pastoral Care in Health Care*. Press Medicine and Law, Lviv, no. 31.

³² VRU (1992), Fundamentals of the legislation of Ukraine on health care: Law of Ukraine of 19.11.1992, № 2802-XII. *Information of the Verkhovna Rada of Ukraine*, no. 4. Art. 19.

³³ H.T. Tereshkevych (2018), *Osnovy bioetyky ta biobezpeky* [Fundamentals of bioethics and biosafety]. Ternopil': Press TDMU, p. 148 (in Ukrainian).

³⁴ *Ibidem*, p. 148.

Modern medicine performs transplants of important organs and blood to save lives. Ukraine has adopted a special Law “On Transplantation of Organs and Other Human Anatomical Materials” (No. 1007-XIV/16.07.1999). This law was replaced on January 1, 2019, by the Law of Ukraine “On the use of transplantation of anatomical materials to humans” (dated May 17, 2018 No. 2427-VIII)³⁵.

The corresponding Law of Ukraine comprises significant ethical restrictions on the transplantation of human organs and other anatomical materials taken from humans or animals. Although the practice of transplantation in Ukrainian medicine lags behind other countries, this Law does not apply to autotransplantation, implantation, and transplantation of gonads, reproductive cells, and live embryos.

Bioethics emphasizes that the brain, pituitary gland, and gonads, which determine a person’s uniqueness and identity, cannot be transplanted.

Donors can be the bodies of the dead³⁶, as well as people who are willing to donate organs without significant harm to their own health and lives to those in dire need. Donation is regarded as an act of donor’s donation.

The Law on “the Application of Human Anatomical Materials”, which was adopted to replace the previous law, retained Article 19, according to which fetotherapy is performed with embryonic tissues and organs derived from abortion material, which is ethically unacceptable. The Law of Ukraine contains the following wording: “Fetal materials for transplantation may be provided in accredited institutions that perform

³⁵ VRU (1999), Law of Ukraine “On transplantation of organs and other human anatomical materials” of 16.07.1999 No. 1007-XIU. *Bulletin of the Verkhovna Rada of Ukraine*, no. 41, Art. 377. – Expired on the basis of: VRU (2018), Law of Ukraine “On Application of Transplantation of Anatomical Materials to Man”, which entered into force on 01/01/2019, dated 17.05.2018 No. 2427-VIII. *Information of the Verkhovna Rada of Ukraine*, 6.07.2018. №51. Art. 15.

³⁶ VRU (2000), Order of the Ministry of Health of Ukraine: Instruction on the ascertainment of human death on the basis of brain death of September 25, 2000, No. 226 – invalidated on the basis of:

VRU (2013), On establishing diagnostic criteria for brain death and procedures for determining the moment of death of a person: Order of the Ministry of Health of Ukraine dated 23.09.2013, No. 821. Retrieved from: <http://zakon.rada.gov.ua/laws/show/z1757-13> (accessed 3.01.2020).

operations on artificial “termination of pregnancy” (abortion) in compliance with the appropriate conditions established by the legislation of Ukraine” (Art. 19)³⁷. Authorities in Ukraine must combat illegal business and trading parts of human embryos sold abroad. The Convention on the Rights of the Child (adopted by the UN in 1989), ratified by the Verkhovna Rada of Ukraine on September 27, 1991 (Resolution 89789-XII), also protects the rights of the unborn³⁸. The European Parliament also approved the ban on the use of abortion materials. According to Directive 98/44/EC on the legal protection of biotechnological inventions (Art. 6), the use of human embryos for industrial or commercial purposes is prohibited³⁹. Nevertheless, this medical technology is allowed in Ukraine.

Certain attempts to influence human chromosomal and genetic heredity through non-therapeutic genetic manipulations aimed at producing human beings selected for gender or other predetermined qualities contradict personal dignity, integrity, and identity, so they in no way can be justified by possible beneficial consequences for humanity⁴⁰.

There is a heated debate in society about the potential risk to human health and the environment from the widespread use of genetically modified organisms (GMOs). The basic principle of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, adopted in 2000 in Montreal, is the principle of caution: without violating WTO requirements, a state may refuse to import GMOs into its territory if it considers such organisms to cause danger⁴¹.

³⁷ VRU (2018), Law of Ukraine “On Application of Transplantation of Anatomical Materials to Man”, which entered into force on 01/01/2019, dated 17.05.2018 No. 2427-VIII. *Information of the Verkhovna Rada of Ukraine*. 6.07.2018, №51. Art. 15.

³⁸ Convention on the Rights of the Child, adopted by UN General Assembly resolution 44/25 of 20 November 1989 (as amended by UN General Assembly resolution 50/155 of 21 December 1995). Retrieved from: https://zakon.rada.gov.ua/laws/show/995_021 (accessed 3.01.2020).

³⁹ Directive 98/44 / EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. *Official Journal of the EU*, L213, 30 July 1998, pp. 13–21.

⁴⁰ Congregazione rer Dottrina della Fede (1987), *Istruzione Donum Vitae*, 22 febbraio 1987. Città del Vaticano: Libreria Editrice Vaticana, p. 72.

⁴¹ Tereshkevych, H. T. (2018), *Osnovy bioetyky ta biobezpeky* [Fundamentals of bioethics and biosafety]. Ternopil': Press TDMU, p. 168 (in Ukrainian).

The Law on “the State System of Biosafety in the Creation, Testing, Transportation, and Use of Genetically Modified Organisms” (2007)⁴², which regulates the handling of GMOs to ensure biological and genetic safety, needs to be revised. However, this law actually legalizes the system of wide circulation in Ukraine of genetically modified organisms and products obtained with the help of transgenes.

On December 14, 2004, the Verkhovna Rada adopted the Law of Ukraine “On Prohibition of Human Reproductive Cloning” (No. 2231-IV), which is based on the principles of respect for human beings, recognition of individual values, the need to protect human rights and freedoms, and insufficient research into biological and social consequences of human cloning⁴³.

Reproductive and so-called therapeutic human cloning and cloning of cells derived from embryonic stem cells are ethically unacceptable. From the standpoint of bioethics, it is permissible to clone cells derived from adult stem cells, but they can change the immune status of the recipient's human body and have a cancerous effect. Therefore, we need to work on improving this process. Cloning of stem cells from umbilical cord blood is optimal as such cells are the most immunotolerant, do not cause significant changes in the immune status of another person, and do not provoke cancer. Law must regulate the legal aspects of the use of umbilical cord blood.

The Law of Ukraine “On Medicinal Products” of 1996 (Art. 2) is not consistent with the Basic Law of Ukraine (Art. 27)⁴⁴, because according to it, medicinal products are substances or mixtures thereof derived from natural, synthetic or biotechnological origin, which are used to prevent pregnancy, prevention, diagnosis, and treatment of human diseases or changes in the state and functions of the body⁴⁵. “How can a substance,

⁴² VRU (2007), Law of Ukraine “On the State Biosafety System for Creation, Testing, Transportation and Use of Genetically Modified Organisms” of May 31, 2007 No. 1103-U. *Bulletin of the Verkhovna Rada of Ukraine*, no. 35, Art. 484.

⁴³ VRU (2004), Law of Ukraine “On Prohibition of Human Reproductive Cloning” of 14.12.2004 No. 2231-YU. *Bulletin of the Verkhovna Rada of Ukraine*, no. 5, Art. 111.

⁴⁴ VRU (1996) “Constitution of Ukraine”, Retrieved from: <http://zakon5.rada.gov.ua/laws/show/en/254%D0%BA/96-%D0%B2%D1%80> (accessed 3.01.2020), Ukraine.

⁴⁵ VRU (1996), Law of Ukraine “On Medicines” of 4.04.1996, No. 123/96. *Bulletin of the Verkhovna Rada of Ukraine*, no. 22, Art. 87.

which is made to kill an unborn child, be considered a drug? In a civilized society, such substances are treated as chemical or bacteriological weapons⁴⁶.

Random sexual intercourse has become particularly prevalent in recent years thanks to the efforts of the International Planned Parenthood Federation (IPPF), which focuses exclusively on contraception. In different regions of Ukraine, the number of sexually transmitted diseases has increased 4–10 times. The way out should be seen not in the search for and spread of more effective and safer contraceptives (even if they were contraceptive, not abortive), but in the awareness of the destructive effects of sexual freedom and its restriction by moral standards⁴⁷. State programs on the nation's reproductive health are close to the IPPF policy – contraception and sex education⁴⁸. Contraceptives, depending on their varieties, often act as abortive ones; contradict the nature of both man and woman, as well as their deep unity; lead to miscarriages; cause secondary infertility; endanger the life and health of a woman and offspring. After all, a person has the natural methods of recognizing the days of fertility, which, in contrast to the use of contraceptives, involve marital intercourse, which, although it does not give rise to a new life, remains open to it.

⁴⁶ Nazar, N.O. (2009), On the need to amend the legislation of Ukraine in the field of health care as a mechanism of demographic policy. Proceedings of the Democratic Governance in the Context of Global Challenges and Crises (Ukraine, Lviv, 2–3 April). Lviv: Press LRIDU NADU, pp. 519–522.

⁴⁷ H.T. Tereshkevych (2018), *Osnovy bioetyky ta biobezpeky* [Fundamentals of bioethics and biosafety]. Ternopil': Press TDMU, p. 127. (in Ukrainian).

⁴⁸ CMU (1995) About the National Family Planning Program for 1995–2000: Resolution of the Cabinet of Ministers of Ukraine dated 13.09.1995, No. 736. Retrieved from: <http://zakon.rada.gov.ua/laws/show/736-95-%D0%BF>, (accessed 03 Jan 2020); CMU (2001), About the National Program "Reproductive Health 2001–2005" Resolution of the Cabinet of Ministers of Ukraine of March 26, 2001 No. 203. Retrieved from: <http://zakon.rada.gov.ua/laws/show/203/2001> (accessed 3.01.2020); CMU (2006) On approval of the Concept of the State Program «Reproductive Health of the Nation for 2006–2015»: Resolution of the Cabinet of Ministers of Ukraine No. 244 of April 27, 2006. Retrieved from: <http://zakon.rada.gov.ua/laws/show/244-2006-%D1%80> (accessed 3.01.2020); CMU (1996), On approval of the Concept of the National Program "Reproductive and sexual health of the nation for the period up to 2021": draft decree of the Cabinet of Ministers of Ukraine dated 16.03.2017. Retrieved from: <https://www.umj.com.ua/article/106030/rozrobleno-program-reproductive-ta-statevogo-healthy-ya-natsiyi> (accessed 3.01.2020).

Confirmation of ensuring the principles of the value of life is at least the abolition of the death penalty on February 22, 2000, by the People's Deputies of Ukraine⁴⁹. On December 29, 1999, the Constitutional Court of Ukraine recognized that the death penalty contradicted the Constitution of Ukraine (Art. 3), thus finally closing the way to its restoration. In this regard, in 2000 the Verkhovna Rada of Ukraine amended the Criminal Code of Ukraine, which finally removed the concept of "the death penalty" from the official list of criminal penalties in Ukraine. The absence of the death penalty is a prerequisite for a state to remain in the Council of Europe. From the standpoint of bioethics, the state is not legitimate to claim the highest human value – the natural right to life, which has a primary non-state nature and does not depend on the state. Modern society is able to overcome crime successfully by methods that neutralize the offender, but do not deprive him/her of the opportunity to change his/her life. An individual, even the cruelest criminal, can never become a thing, but always remains a human. Ukraine has introduced the maximum penalty of life imprisonment for particularly serious crimes, which is proof of the humanity of the state.

Regarding euthanasia there is no special legal act in Ukraine, where the right to life is guaranteed to every citizen by the relevant articles of the Constitution (Art. 3, 27, 64), and the right to health care and medical care are guaranteed by the Constitution of Ukraine (Art. 49)⁵⁰. However, this issue is regulated by the "Fundamentals of the legislation of Ukraine on health care" (Art. 52)⁵¹, the Criminal Code of Ukraine (Art. 139, 115)⁵², where euthanasia is strictly prohibited, and when com-

⁴⁹ VRU (2000) On the ratification of Protocol No. 6 to the Convention for the Protection of Human Rights and Fundamental Freedoms, concerning the abolition of the death penalty, 1983: Law of Ukraine of February 22, 2000 No. 1484-III – p. 104. Retrieved from: https://zakon.rada.gov.ua/laws/show/994_802 (accessed 3.01.2020).

⁵⁰ VRU (1996), "Constitution of Ukraine". Retrieved from: <http://zakon5.rada.gov.ua/laws/show/en/254%D0%BA/96-%D0%B2%D1%80> (accessed 3.01.2020).

⁵¹ VRU (1992) Fundamentals of the legislation of Ukraine on health care: Law of Ukraine of 19.11.1992, № 2802-XII. *Information of the Verkhovna Rada of Ukraine*, no. 4, Art. 19.

⁵² VRU (2001) "Criminal Code of Ukraine", *Lists of the Verkhovna Rada of Ukraine*, vol. 25–26, Art. 131.

mitted would qualify as premeditated murder. However, today the legal framework is unclear in Ukraine, which is a matter of concern. Public authorities should take care of the appropriate legislative solution to the problem, providing mechanisms for monitoring compliance with the law, and introducing palliative therapy – alleviating the suffering of terminally ill people instead of euthanasia. An effective confirmation of this position is the creation of hospices – special institutions that provide decent care and treatment of terminally ill people who need spiritual and moral support the most.

In the context of the requirements of bioethics, society must also take care of people with special needs for their general and diverse integration into society and improve the quality of life.

Belonging to the human race is a recognition of the right to dignity of everyone, and this is enough because the other attributes (beauty, success, health, wealth, intelligence, adulthood, etc.) equate with the secondary ones and are incapable of characterizing dignity, which is entirely contained in this belonging. Reflections on the right to life of the fetus are placed in this context, because “the first manifestation of human dignity is the right to life – it is an intellectual gesture that brings the truth back to it and deprives it of ambiguity”⁵³.

A horizontal line running through all higher levels of civilization can graphically represent the historical movement, which has hitherto recognized human dignity and human rights. The age in which we live urgently requires the completion of this process also along the vertical line, which involves equal dignity, recognition of fundamental human rights, and the right to life of every human being from the moment of fertilization to God-ordained departure (natural death).

Scientific studies of the nature of the human embryo have shown that it is a unique human being, has all the characteristics of the human personality, and is controlled by the personal genome of its own project-program of life from the moment of fertilization.

It is very important that all people realize the human nature of a person in his/her embryonic state. This is especially true for those who pass

⁵³ M. Casini (2001), *Il diritto alla vita del concepito nella giurisprudenza europea le decisioni della Corti Costituzionali e degli organi sovranazionali di giustizia CEDAM*, Padova, p. 349–350.

legislation to legalize or prohibit abortion, which is not only an ethical crime but also a direct violation of fundamental human rights, a criminal offense against human life, the function of the defense and protection of which is entrusted to the state.

It can be argued that the development of medical science, biology, technology poses a problem to society and the state that involves regulating legal relations concerning the morality of human behavior in the biological and medical field and in the health care system. There is a need to review the main legal documents that define the functioning of the health care system and to issue new ones, as well as to insert appropriate amendments to the basics of state legislation taking into account the provisions of bioethics.

The implementation of the principles of bioethics in the context of lawmaking will contribute to the establishment of these principles not only in regulations but also in their actual implementation.

4. Conclusions from the study and prospects for further exploration in this direction

The principle of the inadmissibility of discrimination in the name of the equal dignity of all human beings must apply to all periods of human existence from the moment of fertilization to natural death, covering special stages (phases): initial, suffering and dying.

Public officials have to provide regulatory support for health care reform based on the values and principles of bioethics, which will serve the interests of every human, his/her dignity, and unique value.

Public authorities need to involve social institutions represented by reputable experts in bioethics, physicians, and community activists, in which the regulatory support for health care reform in the context of bioethics requirements will be safe and beneficial to society as a whole.

Governmental officials should develop measures to introduce the teaching of bioethics into the system of training, retraining, and advanced training of public servants.

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Summary

The demographic situation in Ukraine makes public authorities think about the problem of the value and dignity of human life.

The task of bioethics is to raise ethical and moral requirements to a higher level, including the spiritual level of health care workers, and to harmonize the existing health legislation with its principles.

The proposed article is an attempt to eliminate the gap in the regulatory improvement of the health care system on the values and principles of bioethics.

Many definitions used by Ukrainian law are contingent, imperfect, and contradictory to bioethics.

The purpose of the publication is to provide a scientific and theoretical substantiation of the necessity of normative and legal improvement of the health care system on values and principles of bioethics, which will serve the interests of a person, his/her dignity and unique value.

The absence of consistency in the legislation gives rise to the pluralism of interpretations about the beginning of a person's life, which is a significant drawback in the legal field since this point concerns the inherent human right to life.

The basis of inadmissibility of discrimination in the name of the equal dignity of all human beings may concern all periods of human existence from the moment of fertilization to natural death, covering special stages: initial, suffering and dying.

Public administration bodies need to involve social institutions represented by reputable bioethics experts, scientists, doctors, public activists, with the help of which the regulatory support for health care reform will be safe and beneficial for the whole society.

Keywords: public administration, reform of the health care system, regulatory support, the Basics of Ukrainian legislation of health care, the Constitution of Ukraine, principles of bioethics, an inherent human right to life, value and dignity of human life