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LEGAL STATUS OF BIOETHICS: INTERNATIONAL EXPERIENCE AND NATIONAL CHARACTERISTICS

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Abstract

The work presented explores the legal status of bioethics. In the modern world of scientific and technological progress, ethical norms are becoming increasingly important in order to reduce the negative impact on human life and health of certain factors arising from scientific and technological progress. To a large extent, this applies to medical activities, and in particular to their special direction - biomedicine. Current bioethical norms are considered in the work. Authors investigate the Russian legislation, the legislation of foreign countries, international legal norms regulating the right of the personality for health protection, anyway connected with bioethics. The views of authors - the brightest representatives of domestic and foreign science, on the essence of bioethics and its relationship with law are given.

Keywords

Bioethics - Biomedicine - Principles of bioethics - Morals - Morality - Experience

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Introduction

The development of human civilization inevitably creates a set of global problems on which its survival depends today. Today, these are, above all, the problems of peaceful coexistence between States and peoples, environmental security, demography, health and the related quality of life. The world community and individual States are combating these problems by developing institutional, legal, technical and other mechanisms for solving them. However, the solution to a number of problems arising in public relations lies in a specific plane - ethical. There are a number of issues, such as the definition of the boundaries of life and death, the moral and legal status of an embryo, conceived in vitro, the justification of surrogate motherhood, human genetic engineering, cloning, the moral aspects of research involving humans as a subject, the production and safety of consumption of genetically modified agricultural products, nanotechnologies in medicine, etc¹. This circle covers all aspects of human life – from his birth to his death, and they are united by the priority of the main, universal values: life, health, well-being, justice². The solution of these issues is impossible without the use of ethical instruments, which is the basis for the emergence in the 70s of the XX century of a special direction of ethics bioethics.

Created thanks to the efforts of American biochemical V.P. Potter³, bioethics took up their discussion, reflection and search for solutions, using an interdisciplinary approach, involving the general public and seeking political solutions. In recent years there has been an expansion of the discourse of the bioethical field, bioethics as a scientific direction has huge prospects and already real support of representatives not only of natural sciences. Thanks to the American doctor A. Hellegers, who today can rightly be called the «main architect of the ideas of this science»⁴, there was an interpretation of bioethics as a new way of understanding and solving moral conflicts of high-tech medicine. Bioethics in its short period of existence found recognition and became a full member of the humanities, working closely with biology and medicine, became a social movement in the academic world, in biomedical sciences, governments and the media⁵.

In connection with the above, the need to study bioethics and its role in regulating relations in the field of health protection of citizens is updated.

Methods

The work used various methods of research, the basic of which was the dialectical method of knowing reality. The use of the historical method combined with it revealed the causes and marked the moment of the emergence of bioethics as science. The method of transition from general to private allowed to present bioethics as one of the directions of

¹ F. Nezhmetdinova, "Global challenges and globalization of bioethics", Croatian Medical Journal Vol: 54 num 1 (2013): 83–85 y V. G. Bogomyakov, "Contemporary Geopoetics in the Context of the Formation of a New Geospatial Discourse", Rupkatha Journal on Interdisciplinary Studies in Humanities Vol: VIII num 4 (2016): 106-111.

² D. Callahan, Bioethics. Encyclopedia of bioethics (New York: Simon & Shuster Macmillan, 1995).

³ V. R. Potter, Bioethics: Bridge to the future (New York: Prentice-Hall, 1971).

⁴ A. Hellegers, Bioethics center formed. Chemical and engineering news. 1971.

⁵ F. T. Nezhmetdinova y M. E. Gurylyova, "Russian School of Bioethics: a quarter of a century of development", Kazan Medical Journal Vol: 99 num 3 (2018): 521-527.

medical ethics, the method of analysis and synthesis determined its connection with biomedicine. The comparative-legal method made it possible to identify positive aspects of the use of bioethics in the international legal field, to determine the possibility of their continuity for Russian legislation.

Results and findings

Today, it is common to associate the whole set of ethical problems related to medicine with the concept of bioethics. However, one of the most important points for bioethics is the philosophical analysis of existing moral and ethical problems, which helps to bring into line real and necessary, actual and due. Therefore, there are many approaches to the definition of the concept of bioethics: from treating it as a set of rules and principles of correct doctor behavior to understanding it as a section of philosophical knowledge of the principles and foundations of morality in the medical profession. Turning to the content of the concept of «bioethics», it can be noted that its legal definition is absent. Some scholars have proposed author's definitions of the concept. It seems that one of the most accurate is the definition formulated by N.E. Krylova, according to which bioethics is «a set of rules of conduct governing relations (1) between an individual and a subject of biomedical activity. (2) between several subjects of biomedical activity and (3) between the state and one or more subjects of biomedical activity regarding to use of modern biomedical technologies in various spheres: transplantology, thanatology, genetics, reproduction, etc. In another sense, bioethics acts as a doctrine of the rules of conduct of subjects of biomedical activities on the application of modern biomedical technologies»⁶. According to Y.D. Sergeev and A.A. Mohov, bioethics acts as an unconventional source, through which issues in the field of health protection of citizens are regulated⁷.

In view of the above, it seems necessary to consider the relationship between bioethics and law. So, N.N. Sedova considers the interaction of these categories through the ratio of natural to positive law, pointing out that morality is part of positive law, and positive law is based on moral norms. Those that are most significant to society are enshrined as legal laws. According to the author, the specificity of bioethics is that in terms of the rigidity of regulation it represents some unique formation on the verge of natural and positive law. It is no longer morality, but not yet right⁸. In the context of the question under study, let us agree with the opinion of M.N. Maleina, which states that the attribution of bioethics to the source of law is not consistent with the properties of the normative legal act (general obligation, orientation towards the generation or termination of legal consequences, repeated application)⁹. On the basis of the above it is represented that norms of bioethics are moral, moral guidelines of implementation of medical activity, without being at the same time an independent source of law. Based on the content of the principles of bioethics, the legislation regulating legal relations in the field of health protection of citizens is being transformed. The main function of bioethics is to formulate and select ethical principles, the most significant of which can be incorporated into legal norms.

⁶ N. E. Krylova, Criminal and bioethics: criminal legal problems of application of modern biomedical technologies: dis. Dr. J., Sciences (Moscow, 2006).

⁷ Yu. D. Šergeev y A. A. Mohov, "Bioethics - non-traditional source of medical law", Medical Law num 2 (2007): 44.

⁸ N. N. Sedova, Bioethics (Moscow: KnoRus, 2018).

⁹ M. N. Maleina, "The Justification of health law as a complex branch of legislation and some directions of its improvement", Medical Law num 3 (2013): 7-14.

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In the traditional sense, the principles of bioethics are a system of provisions establishing the moral and ethical foundations of activity in medicine and biology, which are not known to apply to legal norms¹⁰. However, in medicine, the main principles of bioethics are also expressed in legislation, thereby imposing on the doctor an obligation to comply with them regardless of their worldview and nature. We will follow the legal reinforcement of bioethical principles. In 1979 the American scientists T. Bichamp and J. Childres in the book «Principles of Biomedical Ethics» called 4 basic bioethical principles: «do not do much harm», «do the benefit», «respect patient autonomy», «justice»¹¹ which became the basis for the further development of bioethics and the adoption on October 19, 2005. The Universal Declaration on Bioethics and Human Rights at the 33rd session of the UNESCO General Conference¹².

It should be noted that certain principles of bioethics have been established at the level of national legislation¹³.

In Russia, the legal foundations of bioethical principles in medicine contain in the Federal Law of 21.11.2011 № 323-FZ «About Bases of Protection of Public Health in the Russian Federation¹⁴ – the main source of the Russian medical law: many principles and sanctions for their violation are laid down in the Criminal Code of the Russian Federation, which indicates the special attitude of the State towards the ethics of medical workers. The prototype of the principle «do not harm» is found in the Hippocratic oath, and in the law the concept of «harm caused to human health» appears in the Resolution of the Government of the Russian Federation of August 17, 2007 № 522 «On Approval of the Rules for Determining the Severity of Harm Caused to Human Health» and stands for «Violation of the Anatomical Integrity and Physiological function of human organs and tissues as a result of exposure to physical, chemical, biological and mental factors of the external environment»¹⁵. Article. 45 № 323 – FZ "Prohibition of euthanasia" directly reflects Hippocrates «I will not give anyone the lethal means asked from me»: the law prohibits medics from acting and doing nothing that can lead to the death of the patient, even if the patient himself asks for it¹⁶. Article. 118 of the Criminal Code of the Russian Federation «Causing serious harm to health by negligence» shares the concepts of simple harm and harm as improper performance of professional duties by doctors¹⁷. Harm to health such as infection with HIV is specified separately (Article. 122 of the Criminal Code of the Russian

¹⁰ Code of Medical Ethics of the Russian Federation. Retrieved from: https://mzdrav.rk.gov.ru/ru/index

¹¹ T. L. Beauchamp, Principle of Biomedical ethics (Oxford: Oxford University Press, 1994).

¹² Universal Declaration on Bioethics and Human Rights (adopted by the UNESCO General Conference resolution on the report of Commission III at the 18th plenary meeting, on 19 October 2005). Retrieved from:

https://www.un.org/ru/documents/decl_conv/declarations/bioethics_and_hr.shtml

¹³ A. I. Baksheev; Z. E. Turchina; G. V. Yurchuk; D. V. Rahinsky; A. V. Leopa y T. V. Melnikova, "Medico-psychological support of elderly patients with somatic pathology in doctor-patient relations", Journal of pharmaceutical sciences and research Vol: 10 num 10 (2018): 2506-2509.

¹⁴ Federal Law N 322-FZ. On the Foundations of Protection of Citizens 'Health in the Russian Federation. November 21, 2011. Retrieved from: https://rg.ru/2011/11/23/zdorovie-dok.html

¹⁵ A. I Baksheev; Z. E. Turchina; V. V. Mineev; S. V. Maksimov; D. V. Rakhinskiy y L. U. Aisner, "Euthanasia in modern society: the topicality, practicability, and medical aspect of the problem", Journal of pharmaceutical sciences and research Vol: 10 num 6 (2018): 1360-1363.

¹⁶ The Criminal Code of the Russian Federation N 118 (Moscow: Normatika, 2019). Retrieved from: http://ukodeksrf.ru/ch-2/rzd-7/gl-16/st-118-uk-rf

¹⁷ V. V. Sergeev, Bioethics: a training manual (Moscow: GEOTAR-Media, 2013).

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Federation). The second basic principle of bioethics «do good» implies the active work of the doctor for the benefit of patients. Upon receipt of the qualification document, the Russian doctor in a solemn atmosphere gives an oath in which he undertakes to «devote his knowledge and skills to the prevention and treatment of diseases» (Article, 71 № 323-FZ «The Oath of the Doctor»). An example of active care is prescribed in Article 36 № 323-FZ «Palliative medical care». Also, according to the American philosopher R. Witch, the benefit will be a special, contractual, type of interaction with the patient, which is based on mutual respect and trust¹⁸. This type of relationship is in many ways evident in Article 13 № 323-FZ, «Observance of medical confidentiality». Article 22 № 323-FZ «Information on the state of health» is also considered. The principle of «respect the autonomy of the patient» is set out in the law as «Priority of the interests of the patient in the provision of medical care» (Article. 6 №. 323-FZ) and «Informed voluntary consent to medical intervention and refusal of medical intervention» (Article 20 №. 323-FZ). A doctor can limit autonomy only in the interests of the patient himself, for sanctions are expected for violation of the procedure of the doctor's procedure. Thus, article 128 of the Criminal Code of the Russian Federation, entitled «Illegal hospitalization to a medical organization providing psychiatric care in stationary conditions», stipulates, as the main penalty for abuse of official position, imprisonment for up to seven years. The principle of justice is enshrined in the Constitution of the Russian Federation. The implementation of the situation in healthcare is manifested in many respects in the social sphere, balancing the market mechanism of resource allocation. Thus, article 8 №. 323-FZ, entitled «Social protection of citizens in case of loss of health», guarantees rehabilitation and care. Article. 6.2 № 178-FZ «Set of social services» defines the issue of medicines, free travel and sanatorium treatment¹⁹. The Federal Law of November 29, 2010 № 326-FZ «On Compulsory Health Insurance in the Russian Federation» extends the action both to working, and to unemployed citizens²⁰.

As a result of the study, it can be concluded that the principles of bioethics in medicine not only establish moral guidelines in the «doctor-patient» relations, but also form the basis of legislative acts, and therefore are mandatory for implementation. This shows the high mission of the doctor in society and the special responsibility of the profession at the personal and civil legal level²¹.

At the same time, a significant number of ethical issues (interaction between the doctor and the patient, provision of medical services and other aspects of the activity under consideration) are outside the legal regulation. In our State, in addition to the ones discussed above, there are other laws that regulate, to varying degrees, certain issues related to bioethics. Researchers note their shortcomings. For example, it is rightly argued that the subject matter of the regulation of the Law «On State Regulation in the Field of Genetic Engineering Activity»²² is very narrow and does not extend its effect to the procedure for

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¹⁸ The Federal Law № 178-FZ. About the State Social Help. July 17, 1999. Retrieved from: https://rg.ru/1999/07/23/socpomosch-dok.html

¹⁹ Federal Law N 204-FZ. On Compulsory Medical Insurance in the Russian Federation. July 26, 2019. Retrieved from: https://rg.ru/2019/08/02/budget-ffoms-dok.html

²⁰ A. I. Baksheev; Z. E. Turchina; O. V. Andrenko; V. V. Filimonov; D. A. Nozdrin y G. V. Yurchuk, "Geriatric patients: compliance issues and ways of its optimization", Prensa Medica Argentina Vol: 105 num 9 (2019): 501-509.

²¹ Federal Law № 86-FZ. On State Regulation in the Field of Genetic Engineering Activities. July 5, 1996. Retrieved from: http://www.kremlin.ru/acts/bank/9692

²² E. A. Epifanova, "Legal Aspects of Bioethics in Constitutional and Legal Practice", Young Scientist Vol: 46 num 284 (2019): 120-123.

carrying out genetic engineering activity itself, the possibility of using genetic engineering against a person, his tissues, with the exception of genetic diagnosis and genetic therapy²³. The rights of a person subjected to genetic engineering procedures are not protected by this law, which is a serious gap in the legislation. With such a rather undeveloped legislation, the norms and principles of bioethics are increasingly used to protect patients' rights in the event of a dispute in the courts.

Discussion

It should be noted that certain principles of bioethics have been established at the level of international and national legislation of a number of foreign countries²⁴. The main international legal instruments containing the principles of bioethics are the abovementioned Universal Declaration on Bioethics and Human Rights, the Universal Declaration on the Human Genome and Human Rights²⁵, the Convention for the Protection of Human Rights and Human Dignity in relation to the Application of Biology and Medicine²⁶, The Model Law «On the Protection of Human Rights and Dignity of a Person in Biomedical Research in the CIS Member States»²⁷, as well as a number of others. In a number of countries, bioethical norms are part of the legal regulation. Thus, the French Bioethics Act of 6 August 2004 № 2004-800 regulates the most important issues for modern biomedical medicine relating to reproductive activities, genetic counseling, DNA registration, blood donation, transplantation, etc. This law also regulates the education and activities in France of an independent specialized body in the field of bioethics, the National Advisory Committee on Ethics and Life and Health Science. Bioethics councils, designated as independent bodies, are being formed in many countries, particularly in Europe. The Additional Protocol to the «Convention on Human Rights and Biomedicine in the Field of Biomedical Research» of January 25, 2005 specifically emphasizes the independence of the Ethics Committee, which is the basic principle of its organization²⁸. European experience researchers highlight 2 types of ethical committees in medical institutions: research ethics committees that focus on analysis of medical research involving people, and health ethics committees that focus on the moral aspects in patient care²⁹.

²³ A. I. Baksheev; D. A. Nozdrin; Z. E. Turchina; O. Y. Sharova; G. V. Yurchuk y D. V. Rakhinskiy, "Bioethical principles and mechanisms for regulation of biomedical research", Journal of pharmaceutical sciences and research Vol: 10 num 4 (2018): 889-892.

²⁴ The Universal Declaration on the Human Genome and Human Rights. The UN General Conference on Education, Science and Culture. 1997. Retrieved from: http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

²⁵ Convention for the Protection of Human Rights and Dignity in Relation to the Application of Biology and Medicine. The Committee of Ministers of the Council of Europe. 1996. Retrieved from: http://docs.cntd.ru/ document/901808464

²⁶ The Model Law "About Protection of Human Rights and the Dignity of a Person in Biomedical Research in the State Parties of the CIS". The 26th plenary session of Inter-Parliamentary Assembly of the State Parties of the CIS № 26-10, 2005.

²⁷ G. B. Romanovsky y O. V. Romanovskaya, "Problems of legal regulation of biomedical technologies in Russia and abroad", Genes and Cells Vol: 11 num 1 (2016): 75-81.

²⁸ KI. Korobko, The Role of Bioethics in the Regulation of Relations in the Field of Public Health Protection". Spatial Development Management of the European North of Russia: Socio-Economic, Political and Historical Aspects Materials of the All-Russian Scientific Conference (with international participation), 2019.

²⁹ N. A. Baieva; D. O. Burkin; T. F. Vysheslavova y S. A. Lukinova, "Current Problems Faced by Russia in the State-Legal Policy in Social Partnership in the Labor Field", Journal of Advanced Research in Law and Economics Vol 9: num 5 (2018): 1564-1570.

As we can see, in France, bioethics norms are in legal form, thus directly participating in the legal regulation of the relevant relations. The activities of ethical committees in France and a number of countries in Europe also indicate a more serious attitude towards bioethics norms and ethical control in these countries.

Thus, bioethics is formally in the non-legal field in the Russian Federation, however a number of its elements, such as basic principles, are gradually perceived by the legislator, which takes them into account in the development of new rules of law, and the norms themselves are increasingly perceived by the judicial authorities in their decisions.

Conclusion

Studies have found that bioethics norms differ from legal norms in that they are not elements of legal regulation and come from morality. However, given the rapid development of biomedicine technologies, the legislative power of the Russian State, when adopting normative legal acts, should take into account not only the ideas of the legal consciousness of society and the moral culture of the population of the country, but also the relationship between the norms of law and the norms and principles of morality, including the use of the foundations of bioethics. Thus, the law that has accepted these foundations will become humane and fair. Both morality and law serve a common purpose, namely, human dignity. Thus, the systemic integrity of social norms, including biotic norms, will ensure the normal, comprehensive emergence, development, functioning, relationship between the regulations of social relations and the relations of man and mankind to the living world. The central task of law in the future will be the possibility of combining bioethical norms with legal norms and using the former as a fundamental regulator. It seems necessary to continue the work aimed at incorporating the provisions of bioethics into the system of Russian law in order to respect the interests of the patient and to develop uniform law enforcement practices.

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