# BIOETHICS, LAW AND INTERESTS OF FUTURE GENERATIONS — SOME PRACTICAL AREAS OF COMMON INTEREST

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The article defines the term 'bioethics' taking into account the common regulatory act, shows the interrelation between bioethical and legal regulations, and defines the mechanisms that enhance and improve effectiveness of ethical standards by turning them into legal regulations. Basic regulatory legal acts such as laws and subordinate acts in health regulation are reviewed and analyzed for the presence of an ethical constituent. Critical areas in the regulatory acts are specified; certain ways of their ethical transformation are mentioned. Insufficient ethical substantiation of regulatory provisions in the body of legislation and lack of universal declarative regulations are found. The role of a new subject of bioethics and law (future generations), which significantly expands the area of ethical issues, including applied medical sciences, has been denoted. The conflict between modern ethics and interests of future generations can be a complex issue and should be solved immediately on a constant basis. Ethical and legal principles of future generations — precaution and non-regression — were introduced. It is indicated that the standards of ethical and legal regulation of interests of future generations should be developed.

**Key words:** bioethics, law, health care, legislation, clinical research, ethics, principles of law, legal personality, future generations, genetics

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# БИОЭТИКА, ПРАВО И ИНТЕРЕСЫ БУДУЩИХ ПОКОЛЕНИЙ — НЕКОТОРЫЕ ПРАКТИЧЕСКИЕ ТОЧКИ СОПРИКОСНОВЕНИЯ

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В статье дано определение биоэтики исходя из общепризнанного нормативного акта, показана взаимосвязь биоэтических и правовых норм, определены механизмы усиления и улучшения эффективности этических норм путем их превращения в правовые нормы, т.е. легализации. Разобраны основные нормативно-правовые акты — законы и подзаконные акты в сфере охраны здоровья с анализом на присутствие этической составляющей. Обозначены уязвимые места в нормативных актах и указаны некоторые пути их этического преобразования. Выявлены недостаточное этическое обоснование нормативных положений в общем массиве законодательства и отсутствие полноценных декларативных норм. Обозначена роль нового субъекта биоэтики и права — «будущих поколений», который значительно расширяет круг этических вопросов, в том числе и в прикладных медицинских науках. Конфликт между этикой современности и интересами будущих поколений может представлять собой сложную проблему и должен быть решаем уже сейчас, причем на постоянной основе. Введены этико-правовые принципы будущих поколений — предосторожности и нерегрессности. Указана необходимость разработки норм этического и правового регулирования интересов будущих поколений.

**Ключевые слова**: биоэтика, право, охрана здоровья, законодательство, клинические исследования, этика, принципы права, правосубъектность, будущие поколения, генетика

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Bioethics — what is it? Considering it from the point of view of the science of values, it seems to us that bioethics is, first of all, a set of certain values and procedures for applying these values in practice. Asking the question of finding a definition of the concept of bioethics, let us turn to the internationally recognized act — the "Universal Declaration on Bioethics and Human Rights of UNESCO" of 2005 [1], which states that the scope of the declaration: "Ethical issues relating to medicine, life sciences and related them technologies in relation to humans, taking into account their social, legal and environmental aspects" [1]. Actually, this is a brief definition of bioethics. What is important to emphasize here is an indication of the mandatory legal aspect of bioethics. Thus, the answers to ethical questions and dilemmas are also found in the legal system, and even more than that, the set of values of bioethics is contained in the rules of law or should, if possible, be partially contained in them. The legal system is thus the source in which we must seek answers to most of the bioethical questions that interest us. Moreover, we must never forget that bioethics is a practical institution and social relations that are included in the range of its interests are simply obliged to be regulated by the state due to their exceptional importance for society, and such a regulator is the law — the rules of law. Another important conclusion that follows from the above is that any value of bioethics, any of its provisions should not contradict legal norms, even without being included in the law.

Is the above definition of the concept "bioethics" complete? It seems to us that the subjects and objects of bioethics lie not only in modernity, in the present time, and it is impossible to develop concepts of bioethics only in relation to the current or slightly distant moment. What standards of bioethics will be in 50–100 years we need to think now and anticipate possible future relations in modern standards, especially in the field of new technologies, for example, in operations with the genome, artificial intelligence in healthcare. Only then will our behavior be responsible. Thus, a new subject of bioethics appears on the

arena — future generations, posing even more questions than real relationships.

**"**We, the multinational people of the Russian Federation, based on responsibility for our Motherland before present and future generations, accept the Constitution of the Russian Federation," says our Constitution at its very beginning, showing the exceptional importance of the institution of future generations [2]. We can even say more — a new conflict field has emerged between the ethics of the modern generation and the ethics of future generations. But any concept will remain just an optional guide to action and an ephemeral philosophical construct without reliable anchoring. In what ways can bioethical rules be established that protect future generations? The best and most reliable way is through law. But the law is vast, and the best place to start is with its most basic and reliable sources — principles. The principles of the rights of future generations are the most reliable mechanism. Let's try to formulate them. The first is the precautionary principle. Its meaning is that as a result of the decisions made, we must make sure whether the situation of all interested parties is not worsening, including projection into the future. The second is the principle of non-regression. He says that the already achieved level of protection cannot be reduced; new bioethical norms should not worsen the situation of subjects in comparison with existing ones. But this is not always possible and it is also necessary to provide in some cases the possibility of reducing the level of protection with an adequate analysis of the balance of risks and in order to protect other fundamental rights, but the principle of proportionality must be taken into account and objective evidence of the need for such a step must be applied. Initially, the international doctrine of the rights of future generations considered only issues of ecology and environmental protection, but at the current level of development of social relations, other bioethical issues also become important for us, for example, in the field of genetics — these are the rights of unborn descendants of persons subjected to gene therapy or other modification genome. Regardless of the degree and line of kinship in the ascending and descending line, relatives have rights to the common part of the genetic material that unites them to the extent that their interests may be affected by the disclosure of this genetic information or in the event of its modification transmitted by inheritance. This is a new type of personal genetic data, which defines a new vast group of relationships, and which is not yet clear how and to what extent to regulate. This will require, it seems to us, a precise definition and consolidation in legislation of different degrees of kinship from the standpoint of the legal circulation of genetic data; until now this has not been necessary. So today the legislation — Article 14 of the Family Code of the Russian Federation speaks only about close relatives [3]. A more thorough study of the degrees and forms of kinship (direct and collateral lines of kinship) and the introduction of appropriate changes to both the Family and Civil Codes and newly created regulations is required. Thus, we can talk about a new direction — ethics and the law of kinship relations from the perspective of the genetic interests of present and future generations.

Regarding the issue of creating an institutional system for the protection of the rights of future generations, it is necessary to determine the bodies that may be included in it — this could be, for example, the Constitutional Court, the institution of the Commissioner for the Rights of Future Generations recognized in international law, the prosecutor's office, in the field of clinical research — this there may be ethics committees and other bodies.

Let us now consider some ethical aspects and issues related to the relationship between legal and ethical norms, as well as the need to regulate the rights of future generations. The basic law in the field of health protection — the Federal Law "On the Fundamentals of Protecting the Health of Citizens in the Russian Federation" [4] does not contain a definition of the concept of bioethics, but nevertheless the norms of Chapter 2, as fundamental for the entire law, reveal many of the values of bioethics. In by-laws, it should be noted that the concept of "bioethics" is extremely rare.

Therefore, the primary task is to supplement Article 2 of the law "On the fundamentals of protecting the health of citizens in the Russian Federation" with a definition of bioethics, which provides an interpretation of the basic concepts used in the field of health protection.

Next, we will dwell in more detail on the values of bioethics contained in the norms regulating most areas of health care. First of all, speaking about the main act — the Federal Law "On the fundamentals of protecting the health of citizens in the Russian Federation", we will emphasize that Chapter 2 is devoted to the basic principles of health protection. This is a very important chapter, and the principles are provisions that, despite the widespread misconception about their declarative nature, still act directly. Action directly means that they do not require additional reference to other individual norms (articles), but work independently and you can and even need to refer to them directly to defend your position — bioethical and legal. Separately, we can also highlight in this law the current, modern Article 96 [4], which deals with monitoring the safety of medical devices, and from the standpoint of the rights of future generations, it seems to us that it needs to be supplemented with the following content: "Monitoring the safety of medical devices must contain "implementation of precautions and consideration of possible adverse consequences in the future." It is also very important to imbue Chapter 2 of the same source with additional ethical content and to more fully reveal some of the values. For example, Article 6 of the above Federal Law: "Priority of the interests of the patient in the provision of medical care" can be clarified and stated in the following form: "The interests and well-being of the individual patient (person) must prevail over the interests of science or society" [4].

Some of the norms of bioethics that regulate the most important social relations, or rather, deviations from these bioethical norms, are enshrined in the Criminal Code in the form of crimes, therefore, criminal liability measures are provided for violation of these norms [5]. The array of criminal norms is, of course, gradually replenished with new elements as social relations become more complex. International law even attempts to develop the institution of criminal liability to future generations. Thus, it seems to us that we should soon expect the establishment of criminal liability for the unlawful use of genetic data, resulting in a violation of the interests or harm to the health of present and future generations; for concealing information about circumstances that pose a danger to the life or health of future generations; for violation of sanitary and epidemiological rules and regulations, resulting in a violation of the rights of future generations.

Bioethical values related to vulnerable communities and individuals, such as those suffering from mental and behavioral disorders, are very important. Therefore, the Law "On Psychiatric Care and Guarantees of the Rights of Citizens in its Provision" [6] is so urgent, the preamble of which states that the lack of proper legislative regulation of psychiatric care may be one of the reasons for its use for non-medical purposes, causing harm to human health dignity and rights of citizens, as

well as the international prestige of the state. Therefore, we can draw a very important conclusion — all bioethical norms governing relationships in the lives of any vulnerable categories must be fully and comprehensively enshrined in legal acts.

There is a Federal Law "On State Regulation in the Field of Genetic Engineering Activities" [7]. In the designated scope of the law, we see that it: "Regulates relations in the field of environmental management, environmental protection, environmental safety and human health protection that arise during the implementation of genetic engineering activities. The procedure for carrying out genetic engineering activities and applying its methods to a person, tissues and cells within his body, with the exception of gene diagnostics and gene therapy (gene therapy), is not subject to regulation by the Federal Law" [7]. Analyzing this act, we find a complete lack of ethical and legal regulation issues of gene diagnostics and gene therapy, which are stated in its subject. This gap needs to be corrected now. Moreover, these aspects also lie in the sphere of interests of future generations.

But the main directions of state regulation in the field of genetic engineering activities are, according to Article 5 of this law: "Improving human living conditions and protecting his health" [7], valuable here is an indication of the aspect of improving human living conditions, because this ethical provision is rare for legislative acts and, as it seems to us, can be used more and more often in legal norms.

Bioethical norms embedded in the rules of law, as we previously analyzed using the example of the norms of the Criminal Code, cannot work effectively without sanctions, but when the act does not yet constitute a crime, but only constitutes an offense, a misdemeanor, then the norms contained in the law come to the rescue. "Code of the Russian Federation on Administrative Offenses" [8]. For example, violations of legislation in the field of ensuring the sanitary and epidemiological well-being of the population may indirectly affect the rights of future generations and, accordingly, with the detailed development of the institution of rights of future generations, this act should be supplemented with new norms.

In some cases, reliable personal identification is necessary in practice. The procedure of mandatory genomic registration used for this is also difficult from an ethical point of view, especially with the issue of determining the grounds for it and, therefore, requires regulation by law. This law is called "On State Genomic Registration in the Russian Federation" [9]. The following subjects are subject to this registration: persons convicted and serving a sentence of imprisonment for committing crimes; unidentified persons whose biological material was seized during investigative actions; persons suspected of committing crimes, accused of committing crimes; Unidentified corpses are subject to mandatory state genomic registration. As we can see, this list represents vulnerable categories, and the law itself, in our opinion, therefore requires mandatory consolidation in it of ethical principles of working with both genetic data and subjects.

The next regulatory act is the law "On Biomedical Cell Products" [10], it regulates relations in this area. From the point of view of bioethics, we are interested in Article 3, which specifies the principles for carrying out activities in the field of circulation of biomedical cell products: "Voluntariness and gratuitousness of donation of biological material; inadmissibility of purchase and sale of biological material; the inadmissibility of creating a human embryo for the purpose of producing biomedical cell products" [10]. As we can see, these standards are entirely aimed at removing this area from commercial circulation to prevent, among other things, ethical abuses. It is extremely important, in our opinion, to extend these principles to the circulation of genetic material as well.

It is impossible not to mention the Federal Law "On the Donation of Blood and Its Components" dated July 20, 2012 N 125-FZ, Article 4 of which provides the basic ethical principles of donating blood and (or) its components: the safety of donor blood and its components; voluntary donation of blood and (or) its components; maintaining the health of the donor while performing the donor function; ensuring social support and respecting the rights of donors; encouragement and support of free donation of blood and (or) its components. We consider it appropriate to supplement these principles in the law with the principles of availability of blood and its components and guarantees of state support for the blood service.

Let us now turn to the lower level of regulatory legal acts, the so-called by-laws. As an example, we can cite the National Standard of the Russian Federation "Accessibility of urban infrastructure facilities for people with disabilities" [11]. Having reviewed it, we discovered that it lacks an explanatory ethical preamble, although its purpose is clear and understandable based on the title of the act. Ethical justification in documents related to vulnerable categories is mandatory, in our opinion, regardless of the level of the act.

There is also a Code of Professional Ethics for Physicians [12], it is fully saturated with bioethical norms and should be more widely used in practice, representing a version of soft law. It seems to us that in order to give it greater force, it is necessary to create local regulations on its basis as a collection of norms regulating the direct performance of labor duties.

And finally, professional standards for healthcare professionals contain ethical provisions regarding the observance of medical confidentiality, the doctor's oath, the principles of medical ethics and deontology in working with patients (legal representatives of patients), colleagues. For example, the Order of the Ministry of Labor and Social Protection of the Russian Federation "On approval of the professional standard "Physician (precinct general practitioner)" [13]. This legal framework has important practical significance when arguing for the imposition of possible disciplinary sanctions on medical workers.

Having analyzed the main national acts regulating the conduct of clinical trials and containing the values of bioethics: Order of the Ministry of Health of the Russian Federation of April 1, 2016 No. 200n "On approval of the rules of good clinical practice" [14]; Rules of good clinical practice of the Eurasian Economic Union (approved by the decision of the Council of the Eurasian Economic Commission of November 3, 2016 No. 79) [15]; National standard of the Russian Federation GOST R 52379–2005 "Good clinical practice", approved by order of the Federal Agency for Technical Regulation and Metrology dated September 27, 2005 No. 232-st [16]; GOST R ISO 14155–2014. "Clinical researches. Good clinical practice" [17], we come to the conclusion that provisions regarding the conduct of clinical trials are contained only at the level of by-laws. In our opinion, it is necessary to provide general provisions on clinical trials and ethical committees, as well as the principles of their functioning, either in the Federal Law "On the Fundamentals of Protecting the Health of Citizens in the Russian Federation" or in a special law, due to their great social significance.

Consolidating ethical standards in legal sources, as we have seen, presents a certain difficulty. As an example, let us cite one ethical obligation contained in a normative act. Thus, in accordance with Article 7, paragraph 21 of the Order of the Ministry of Health of the Russian Federation "On approval of the rules of good clinical practice" [14], the following requirement is

mandatory: “The clinical trial is carried out in accordance with the clinical trial protocol, which contains, among other things, a description ethical aspects of clinical research.” This is one of the few places in the entire scope of legislation where a clear indication is given of the mandatory application of ethical standards, which in itself is significant and should be the “gold” standard, an example for improving the law.

## CONCLUSION

As we have also seen, bioethical norms are presented in legal acts at all levels, but not always fully; their more thorough elaboration and more complete consolidation are necessary, from this the normative acts only become better, clearer, more effective and more accessible. In connection with the emergence of a new subject of law — future generations, new ethical issues and the need to change and supplement legal norms arise.

Raising the question of the new scope of the concept of bioethics, we tried to briefly formulate the general principle: “Law and bioethics, inextricably and consistently, must think and act in the interests of future generations, while protecting the interests of the present.” Thus, our task for the future is to saturate existing and newly adopted legal acts with capacious ethical content — the values of bioethics, which in this way will gradually pass into the legal bed and become much stronger from this.

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