

LEGAL AND ETHICAL EXPERTISE OF GENETIC RESEARCH: ISSUES OF REGULATION AND INSTITUTIONALIZATION

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Although legal regulation of genetic research has been steadily improved, it is still lagging behind promotion of genetic research, especially in the field of development and use of its achievement-based technologies. A distinct feature of this legal area is currently a higher dependence on ethics. This resulted in establishment of a special institution, an ethics committee, that unites the possibilities of ethical and legal expertise giving birth to numerous organizational and substantive issues. Some of them are reflected in discussions about the relationship between moral reflection and legislative processes, epidemiological status of bioethics, etc. For instance, in Russian literature there is a thesis that organization and conduction of ethical expertise is regulated much better than those of legal one and can be implemented within the current legal and regulatory framework. Meanwhile, a need for legal expertise in genomic research and genetic technologies is not inferior but even superior. This is confirmed by deficient legal support of many important decisions taken by the authorities and actions accomplished by research groups. The article reviews opinions of Russian and foreign scientists who provide different assessment of the role of ethics committees and their possible falling within law or ethics. The role and place of ethics committees in the system of rule-making harmonization and law enforcement are specified.

Keywords: genetic research, bioethics, ethical committee, ethics-consistency review, code-consistency review

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ПРАВОВАЯ И ЭТИЧЕСКАЯ ЭКСПЕРТИЗЫ В СФЕРЕ ГЕНЕТИЧЕСКИХ ИССЛЕДОВАНИЙ: ПРОБЛЕМЫ РЕГЛАМЕНТАЦИИ И ИНСТИТУЦИАЛИЗАЦИИ


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Правовое регулирование генетических исследований неуклонно совершенствуется, но все равно не успевает за развитием самих генетических исследований, особенно в сфере разработки и применения основанных на их достижениях технологий. Отличительной чертой данной области права в настоящее время является его более высокая зависимость от этики, что выразилось в создании особого института — этического комитета, объединяющего возможности этической и правовой экспертизы, но одновременно с этим рождающего многочисленные проблемы как организационного, так и содержательного характера. Некоторые из этих проблем отражаются в дискуссиях о соотношении этики и права, эпистемологическом статусе биоэтики и др. Так, например, в отечественной литературе высказывается тезис о том, что организация и проведение этических экспертиз в отличие от правовых регламентировано значительно лучше и может осуществляться в рамках действующей нормативно-правовой базы. Между тем потребность в правовой экспертизе в области геномных исследований и генетических технологий никак не меньшая, если не большая, что подтверждается дефицитом правового сопровождения многих важных решений власти и действий исследовательских коллективов. В статье приводятся мнения отечественных и зарубежных ученых, расходящихся в оценке полномочий этических комитетов и возможности их отнесения к сфере права или морали. Уточняются роль и место этических комитетов в гармонизации системы нормотворчества и правоприменения.

Ключевые слова: генетические исследования, этическая экспертиза, правовая экспертиза, биоэтика, этический комитет

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Concerned that legal regulation of genomic research should be developed and that genetic technologies should be applied, Russian legislators have adopted Federal Law as of 12 April 2010 No. 61-FZ 'On Medicine Circulation' implementing the best global practices. In particular, the legislators have improved regulations and mechanisms of expertise production that provide for special expertise structures, Councils of Ethics. The Law prescribes a list of basic requirements to experts, provision about the council, procedure of its activity, organization and production of an ethical expertise. There is also another document, Executive Order of the Ministry of Health and Social Development of the Russian Federation as of 26 August 2010 No. 753н 'On

Approval of the Procedure of Organization and Conduction of an Ethical Expertise of Possibility to Conduct a Clinical Trial of a Medicinal Product for Human Use and Form of Conclusion from the Ethics Council', regulating the same (registered in the Ministry of Justice of the Russian Federation as of 31 August 2010 No. 18303).

Another Federal Law as of 21 November 2011 No. 323-FZ 'On Fundamental Healthcare Principles in the Russian Federation' mentions ethics committees that ensure compliance with ethical standards by healthcare workers. Specialists are well aware that this can result in additional bureaucratic overload, which can't be effectively confronted yet in real practice of genomic research regulation and use of

genetic technologies [1]. However, the positive experience of ethics committees in modern Russian medicine and science shouldn't be underestimated [2].

Mokhov A. A. justly observes that Federal Law as of 23 August 1996 No. 127-FZ 'Concerning Science and State Scientific and Technical Policy' doesn't have any mention of ethics in the field of scientific research. At that time, it seemed that the scientific society coped quite well with similar issues within existing scientific traditions and research practices. Indeed, scientific expertise organization has always been subjected to regulation by reviewers, opponents, scientific councils, scientific advisors, and departments in universities and research institutes. An ethical aspect assessing the prevalence of the topic or scientific novelty of the obtained results was present, if any, while discussing rather the means selected by a researcher to achieve the purposes than the purposes proper.

Doctors and legal scholars who come across ethical issues intuitively understand that it is impossible to appeal to any moral teaching or ethical theory while formulating the principles of bioethics. In other words, the knowledge of bioethics doesn't mean that general ethics penetrates into various spheres of social experience and respective cognitive practices, whether it be politics, economics, medicine or law. The subordination model of post-Soviet theory of cognition, where knowledge circulates within the philosophical, general and specific scientific levels, is first substituted by the coordination model and then disintegrates. The principles of bioethics are frequently interpreted by lawyers as a result of generalizing long-term generation experience or as legal practices but not as a product of paper-based philosophical considerations or religious revelations [3].

A point of view, in accordance with which bioethics doesn't originate from general ethics, is widely supported by philosophers. Gusseyinov A. A. states that 'the issue of scientific and practical status of certain types of applied ethics can't find a unique solution for now. They don't obviously constitute parts or sections of ethics as science of morality, they belong to respective special areas of knowledge (biology and medicine for biomedical ethics, science studies for science ethics, etc.) to the same or an even a greater extent [4]. The issue about the mode of bioethical knowledge is far from being idle. The morality that substituted moral standards and simple copying of adults' behavior had existed as instructions, lectures and speculations from the very beginning. Tradition-supported authority is essential here. In case of Christian ethics (and any other religious morality), it is about the authority of the Holy Scripture and Holy Tradition, texts and their interpretation. But, eventually, there appeared quite many ethical theories, and their interpretations went beyond all the possible boundaries. That is why the question concerning how ethics can exist in the post-metaphysical epoch has turned into a pressing challenge of the XX century. Should it be based on certain metaphysics or religious doctrine just like it was before? Or is it formed by therapeutic and research practices just like in case with biomedical ethics, and the values of humanity are enough to determine the principles? One of the most pressing current issues is to organize legal and ethical expertise in the sphere of genetic research.

Mokhov AA notes that legal expertise has been quite common within the last two decades, irrespective of the fact whether an employer is represented by business, regulatory and administrative authorities, investigation authorities, courts, etc., whereas ethical expertise in the

field of biomedical ethics is not yet significantly widespread and poorly codified. According to Mokhov A. A., 'though the issue about the ethical expertise with various variations (bioethical, humanitarian, social and ethical, etc.) applicable to innovations, healthcare and genomics is being discussed in the professional community, the issue about the legal expertise is not. However, ethics expertise can't consume legal ones, especially since there can be a conflict between ethical and legal standards in certain cases, thus requiring a complex approach to solving complicated ethical, legal and other issues of modernity' [5].

Meanwhile, the declared issue has been discussed in foreign literature as well. Moore A and Donnelly A believe that ethics committees are currently required to accomplish two tasks. They examine, first, whether research projects comply with the acting legislation (code-consistency) and, second, whether they are acceptable from the ethical point of view (ethics-consistency) [6]. The authors assert that the abovementioned tasks cannot be fulfilled by the same institution because these are different tasks both from the practical point of view, and considering the principles of their operation. In short, Moore A and Donnelly A believe as follows: the issue about the compliance of the considered projects to the legislation occurs due to legal uncertainty. The reason for it consists in quality of the laws proper, and wording of the laws and their gap with practice enquiries, in particular. The project compliance with ethical standards, when experts should focus on correspondence to bioethical principles but not legal standards, is quite another issue. Although codified law should not contradict to ethical standards and principles, the arising situations of legal uncertainty are solved in practice using the means and methods of the law itself due to unclear wording of the law in the field of biomedicine and are not different from other cases solved under conditions of legal uncertainty. At the same time, addressing to ethical arguments while attempting to resolve legal conflicts can destroy the law.

The ethical expertise appealing to the laws won't be considered as satisfactory as well. Moore A and Donnelly A state that 'thinking based on ethical consistency will have a tendency to combine the issue of which factors need to be taken into account during consideration with the issue of which problems are ethical. Emphasis will usually be placed on question whether legality of the suggested activity and scientific quality of the suggestion constitute ethical issues. It is difficult to provide principal answers to the questions, unless somebody appeals to any disputable and reasonably rejected ethical concept, rejecting other similar concepts' [7].

Subsequently, Moore A and Donnelly A mention that according to Aristotle and Mill, ethics encompasses regulatory and justifying speculations in the field of a practical action. At the same time, they state that Kant separates ethics from law and grants the sphere of ethics with limited jurisdiction considering it as a special but incomplete subset of a wider regulative set.

Thus, there occurs an issue of choice between different ethical theories, which obviously should not be a task of any ethics committee or supervisory board. The thought is expressed by Holm S who enters into polemics with Moore A and Donnelly A on the pages of the same edition. According to Holm S, 'research ethics committees do not represent philosophical seminars; they are not intended to develop research projects that could be optimal from an ethical point of view. They have to ensure that the research is ethically acceptable. It means that they need to authorize a deviation

from the law, if the law results in the outcome which is ethically unacceptable' [8].

Holm S. believes that Moore A and Donnelly A are mistaken thinking that ethics committees have to search for an ethically ideal way, whereas in reality, their function is to determine ethically unacceptable, but legally allowed actions within research projects. In other words, ethics committees can influence the law without being a separate source of it. Here it is better to consider the opinion of a reputable Russian specialist in the field of bioethics and medical law. According to Sedova NN, 'being a source of law, bioethics is different from morality, in general, and ethics, in particular. It rather requires legal formalization of its principles being closer to positive law regarding the content and mechanism of standards-compliant regulation as compared with other areas of ethics. Moreover, bioethics is a unity of theoretical and practical constituents, whereas ethics and morality are quite distinct as theory and practice' [9]. Moreover, bioethics can be included both into the structure and the content of law, this being both a soft, and a hard instrument [10].

In the context of the above, Nowotny H and Testa G hold a very curious opinion. They believe that bioethics is not related neither to law, nor to morality, without denying its connection with both of them. They see bioethics as a separate social regulator of a new generation. According to the authors, bioethics is a technology of humanitarian standardization acting as a central instrument of management that can balance 'the maximal possible specter of frequently mutually exclusive interests of a growing number of actors', manage the occurring interdependencies and develop administrative and legal policy in this sphere. Bioethics is considered by the authors as one of three social technologies of humanitarian standardization required to create complex sociotechnical system. Two other systems such as law and governance are not separated from each other and from bioethics, but form a complex sociotechnical complex.

Nowotny H and Testa G see bioethics as a means of building a new society and a means of restructuring its social institutions and values. According to them, 'the purpose is to develop the standards that allow to change and rebuild the forms of life. Thus, a deeper convergence of a molecular age is detected. Human technologies of a certain social maturity are close to biology which is open to setting social goals, accepting legal and ethical restrictions, taken into account from the very beginning, and includes them into its design. The common feature is that both of them represent complex

systems that must be decomposed and reassembled again' [11].

A similar point of view is made by other authors. They note that there are rare examples of successful international regulation of genetic research based on ethical standards and principles of biomedicine. They believe that the appeals to bioethics increasingly remind of the so-called public involvement. 'The stereotype of bureaucratic ethical compliance with the rules no longer corresponds to the purpose in the world of CRISPR twins, synthetic neurons and self-driving cars. Bioethics does not rely on philosophical ideas any longer. Instead, it acts as a dashboard of pragmatic tools, and is managed by experts to the lesser extent' [12]. Politicians, journalists and social activists increasingly act as alternative bioethics experts, displacing specialists with respective advanced degrees and scientific publications.

In an interview, a French journalist asked Heidegger M whether he is ready to write 'Ethics' that could be interpreted as a doctrine of action in accordance with the tradition. 'Ethics?' asked the German philosopher. 'Who can afford this today and on behalf of which authority can this be suggested to the world?' [13]. It is natural that the words of the man who produced a rapidly increased intellectual and spiritual influence on the minds of his contemporaries, flirted with national socialism and paid for that by being banned from teaching could be associated with personal circumstances. The dispute about humanism entered by Heidegger with Sartre can also be explained by personal circumstances. Although more than half of a century has now elapsed, it is still a question today whether ethics can be appealed to as a source of knowledge or as a basis for judgement. Who has a right to speak on behalf and at the request of ethics? Is this right supported by the presence of some publications, influence in the scientific community or good attitude of the reading public? Or should evidence of lifestyle of someone who pretends to be an expert be exploited with his moral character and professional reputation being flawless? These questions make other ones recede into the background: which ethical doctrine must be followed by an expert and which values must be shared by him? To answer the question, it is necessary to remember that principles of bioethical declarations and biomedical conventions, that actually underlie the international biolaw, originate from philosophical seminars, literature, and other similar experience, which expands and specifies the ideas of human nature, dignity and rights.

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