PAGE OF THE EDITOR-IN-CHIEF

УДК 614.2-612.1

ETHICAL PATTERNS OF A NEW FEDERAL ACT

V.I. Petrov
Full Member of the Russian Academy of Sciences, Doctor of Science (Medicine), Professor, Rector of the Volgograd State Medical University of the Ministry of Public Health of the Russian Federation Editor-in-chief, post@volgmed.ru

A Federal Act N 180-ФЗ on "Biomedical cell products" passed on June 8, 2016 by the State Duma and on 15 June, 2016 by the Federation Council of the Russian Federation, came into force on January 1, 2017. To the best of our knowledge, and as evidenced by publications in this journal [1, 2], any legal document has moral implications, particularly a document regulating the attitudes and behavior towards all living things. In this relation the new act is viewed as a great step towards the development of bioethics in Russia. A number of bioethical issues involved in the previous act №323-ФЗ on «The basic issues of protection of human health in the Russian Federation» and №61-ФЗ «Handling of medicines» did not receive appropriate elucidation. The new act contains Article 14 on «Ethical expertise» which sets standards absent from act №323-ФЗ and recapitulates the substance of Article 17 of act №61-ФЗ. On the other hand, questions regarding organization of ethical expertise arise and require further discussion when developing subordinate local acts to ensure effective implementation of the new federal act in medical practice.

Key words: *ethical expertise, biomedical cell products, informed consent, donor of biological material, ethics committee, a clinical trial.*

ЭТИЧЕСКИЕ ПАТТЕРНЫ НОВОГО ФЕДЕРАЛЬНОГО ЗАКОНА

В.И.Петров
Академик РАН, ректор ФГБОУ ВО «Волгоградский государственный медицинский университет» Минздрава России,
Главный редактор журнала «Биоэтика», post@volgmed.ru

8 июня 2016 года Государственной Думой принят, а 15 июня 2016 года одобрен Советом Федерации Федеральный закон N 180-ФЗ "О биомедицинских клеточных продуктах". Он вступил в силу 1 января 2017 года. Как известно, в том числе из публикаций в нашем журнале [1, 2], любой правовой документ имеет нравственное содержание, особенно документ, регламентирующий правила поведения в отношении живого. Новый Федеральный закон в этом отношении является существенным шагом вперед в развитии отечественной биоэтики. В нем четко сформулированы те положения в области биоэтики, которые были отражены, но не объяснены в Федеральном законе №323-ФЗ «Об основах охраны здоровья граждан в Российской Федерации» и в Федеральном законе №61-ФЗ «Об обращении лекарственных средств». В новом законе имеется специальная Статья 14 «Этическая экспертиза», которая устанавливает нормативы, отсутствовавшие в №323-ФЗ, но полностью повторяет Статью 17 №61-ФЗ. В то же время, имеется ряд вопросов по организации этической экспертизы, которые не нашли отражения в законе и должны быть обсуждены в ходе разработки подзаконных актов и других документов, необходимых для его успешного применения в медицинской практике.

Ключевые слова: *этическая экспертиза, биомедицинские клеточные продукты, информированное согласие, донор биологического материала, этический комитет, клиническое исследование.*

The emergence of a new federal act N180-ФЗ on «Biomedical cell products» indicates that new human enhancement technologies have become a reality in our country. Furthermore, they have become commonplace medical practice which, however, requires legal regulation. Theoretical debate on what a person whose health is protected through new cell technologies will be like [2] is replaced by debate on how to use these technologies appropriately. In other words, their use per se is not questioned any longer.

I am pleased to note that the text of the new legislation is consistent with those technological advances that require new regulatory approaches. The act does not contain a lot of red tape; all the statements are clear and well defined which can be considered as a scientific achievement of sorts. In Russia, there is still no bioethical dictionary providing definitions for such terms as biomedical cell product (autologous, allogeneic and mixed), biological material, safety and effectiveness of biological cell products, patient information leaflet, side-effect, adverse reaction, etc. However, all these terms are somehow used in bioethical discourse.

The bioethical patterns of the new act are primarily presented in Article 14; however, not only in this Article. What are the principally new and most valuable things in the new act that have been introduced in bioethics?

1. The act postulates that «Ethical expertise is conducted by the ethics committee set up by the federal executive body in accordance with the applicable law for the purposes of issuing decisions about applications for research involving biomedical cell products» [3, Article 14, Item 1]. In the text they use the term «ethics board» instead of the conventionally used «ethics committee» but that does not change the whole thing. Yet two questions arise here:

- Which document regulates the setting up of this particular federal executive body?
- Can the currently existing ethics committees in medical and research institutions conduct ethical expertise required to review applications for research involving biomedical cell products? Or specific ethics boards must be created?

2. Article 14 Item 3 postulates that «Payment to the expert members of the ethics committee shall be made in accordance with the contract made between the federal executive body and the expert member of the ethics committee at the expense of budget allocations stipulated for this authorizing body for the current year in the amount established by the Government of the Russian Federation» [3, Article 14, Item 3]. Without this new provision in the act, ethical expertise used to be carried out on a free of charge basis. Applicants were only eligible for the reimbursement of transportation expenses, if any were incurred by the expert, or in transporting the patient. However, these cases were relatively rare. Furthermore, Article 17 of act №61-ФЗ contained provisions on payments to be made in the context of ethical expertise but the payment mechanism was not specified. On the one hand, the provision of Article 14 is fair because ethical expertise is time-consuming, involves intellectual and emotional strain; it is highly skilled work that should be well-paid. On the other hand, ethical expertise results in moral evaluation of a particular situation, and moral issues, as we know, cannot be the subject of commerce. This provision is likely to increase corruption risk in the sphere of biomedical cell products.

3. Article 14 also contains a description of the mechanism of setting up ethics boards. The boards' general powers and duties are also outlined in Article 14 of the new act. Unfortunately, federal act №323-ФЗ did not say a word about ethics committees; however, federal act №61-ФЗ regulated the operation of ethics committees which were responsible for reviewing clinical studies of drugs, as mentioned in our previous issues [4, 5]. Therefore, the provision on «Membership of ethics committees, legal regulations concerning the operation of ethics committees, requirements as to the competence and expertise of the members of ethics committees as well as to the organization and conducting of ethical expertise, ethical approval forms are regulated by the authorized federal executive body. The number of representatives of medical and research institutions may not exceed half of the members of ethics committees» is of huge importance not only for biomedical cell technologists but also for clinicians in general [3, Article 14, Item 7]. We are left with the question: the *authorized federal executive body*, which is referred to in the law, what is it? And: What is the procedure of applying for ethical approval like? It is noteworthy that Article 46 on «State regulation of handling of biomedical cell products» postulates that «1. State regulation of handling of biomedical cell products is executed by the federal executive body whose functions include monitoring and auditing in healthcare …» [3, Article 46, Item 1]. Do these acts speak about the same federal executive body or different ones?

4. The act can only be safely and successfully enforced if there exist subordinate local acts that come into force simultaneously with it. It is particularly important in relation to the act under discussion, as it is regarded as a necessary and valuable tool for biomedical cell technologists and clinicians! In addition to all the above mentioned benefits, the act contains an exhaustive list of vulnerable populations that ethics committees must consider when reviewing applications for research involving biomedical cell products. This list includes the military, law enforcement officials, prisoners (Article 31. Rights of patients involved in clinical trials of biomedical cell products). This Article is consistent with

Article 43 of act №61-ФЗ on «Rights of patients involved in clinical trials of new medical products». I would particularly draw attention to the fact that the previous act did not protect the rights of all the vulnerable populations [6].

The new act contains a template informed consent form (Article 33, Item 8) and requirements to the information provided to the donor (Article 2, Item 17; Article 9, Item 10; Article 30, Item 2.6). This is particularly important because debate on the amount and content of information provided to the patient is currently ongoing in bioethics but no effective decisions have been worked out yet.

In conclusion, I would like to congratulate us all on the new act which is very important in practice and holds great theoretical perspectives. We hope that bioethics specialists will discuss the moral limits and consequences of the provisions of the new act on the pages of our journal.

We look forward to your manuscripts relevant to this topic!

Referenses:

1. Sedova N.N. All laws were once norms of morality, but not all moral norms become laws // Bioethics. 2009.- No. 1.- P. 37-42.
2. Sedova N.N., Prize E.V. On ethical examination of bills in the sphere of public health // Bioethics. 2011. № 2. - P. 9-20
3. Federal Law No. 180-FZ "On Biomedical Cell Products" // Rossiyskaya Gazeta - Federal Issue No. 7007 (139), June 28, 2016.
4. Petrov VI, Sedova NN, Donika AD, Adzhienko V.L. What they forgot to say in the new law // Bioethics. 2011. - No. 2.- P. 26-25.
5. Sedova N.N., Prize E.V. On ethical examination of bills in the sphere of public health // Bioethics. 2011. № 2. - P. 9-20.
6. Ethical examination of biomedical research. Practical recommendations. Under the general revision of the corresponding member. RAMS, prof. Yu.B. Belousova. First edition. Moscow. 2005. - Part VIII.
7. Donika A.D. Medical law: european traditions and international trends. Bioethics. № 2 (10). 2012. P.59-62.

Литература

1. Седова Н.Н. Все законы когда-то были нормами морали, но не все моральные нормы становятся законами//Биоэтика. 2009.- № 1.- С. 37-42.
2. Седова Н.Н., Приз Е.В. Об этической экспертизе законопроектов в сфере здравоохранения//Биоэтика. 2011. № 2. - С. 9-20.
3. Федеральный закон N 180-ФЗ "О биомедицинских клеточных продуктах"//Российская газета - Федеральный выпуск №7007 (139), 28 июня 2016 г.
4. Петров В.И., Седова Н.Н., Доника А.Д., Аджиенко В.Л. О чем забыли сказать в новом законе// Биоэтика. 2011. - № 2.- С. 26-25.
5.Седова Н.Н., Приз Е.В. Об этической экспертизе законопроектов в сфере здравоохранения//Биоэтика. 2011. № 2. - С. 9-20.
6. Этическая экспертиза биомедицинских исследований. Практические рекомендации. Под общей редакцией член-корр. РАМН, проф. Ю. Б. Белоусова. Первое издание. Москва. 2005. – Часть VIII.
7. Доника А.Д. Медицинское право: европейские традиции и международные тенденции // Биоэтика.- № 2(10). - 2012. - С.59-62.