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THE ROLE OF DEONTOLOGICAL NORMS IN FORMATION OF LEGISLATION REGULATING THE PROCEDURE OF MEDICAL AND BIOLOGICAL RESEARCH INVOLVING HUMANS

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Кашканова Н. Роль деонтологічних норм у формуванні законодавства, що регулює порядок проведення медико-біологічних досліджень за участі людини.

Стаття присвячена проблематиці правового регулювання медико-біологічного експерименту на людях. Зокрема автором розглядається фактори, що зумовили появу правового регулювання застосування медико-біологічного експерименту на людях, які мають складний характер та пов'язані із необхідністю забезпечення особистих прав і свобод людини, націлені на недопущення їх порушення. Окремо автором аналізується, вітчизняне законодавство України в сфері охорони здоров'я, яке на національному рівні забезпечує правове регулювання окремих питань проведення медико-біологічних експериментів на людях. Автор робить висновки про необхідність наукового переосмислення особливостей договірного регулювання відносин при застосуванні медико-біологічних експериментів на людях та наголошує на потребі вироблення єдиних доктринальних підходів до вдосконалення законодавства України та приведення його у відповідність з міжнародними правовими стандартами в сфері охорони здоров'я. Разом з тим, автор звертає також увагу на необхідність подальшого ґрунтовного наукового дослідження особливостей кримінально-правових відносин, що виникають в результаті проведення таких експериментів на людях.

Ключові слова: права людини, біомедичні дослідження, клінічні випробування, лікарські засоби, інформована згода, зародження і становлення правового регулювання здійснення медико-біологічного експерименту на людях

The range of problems of legal regulation of medicobiological experiments on humans has historical patterns of its origin, formation and development. It characterizes the current state of scientific knowledge and it needs its research and rethinking with a glance to the current processes of development of society, public institutions, medical and biological sciences. In scientific literature scholars reasonably noted that experiments in the sphere of medicine, including experimentations on human, have deep historical roots, arising from the moment of realization of the idea of treatment possibility, and the effectiveness of treatment is based on previous experimental activities. That is why, one should agree with the opinion of scientists that experiments with different degree of complexity were conducted since the medicine appeared. They began with magic rituals when magicians and sacerdotes treated in temples, they were conducted by the first doctors who noted in their minds effects of the random drugs, and fixed them with further verification [1, 219].

The medicobiological experiment develops with the development of mankind, expanding its scope of application, meth-

ods of realization, expanding range of experimental subjects, which included individuals too. This highlights the necessity to establish requirements for medicobiological experiment not only as a phenomenon of medicine and biology, but also as a legal phenomenon. This is primarily due to the need of ensuring, safety and protection of the rights and freedoms of natural persons as an experimental subject.

The current state of medical and biological sciences is determined by considerable intensification, among other relating to:

- Firstly, expansion of the boundaries of medicobiological intervention in the human organism;
- Secondly, increasing of the risk of medicobiological experiments;
- Thirdly, the needs for the invention of new methods and ways of countercheck and fighting against people's diseases;
- Fourth, the need to counter illegal use of human organism for medical experiments.

The deepening of socio-economic stratification of society, the expansion and strengthening of world's conflicts increases the risk of excessive use of these factors and involvement of a person in participation in medicobiological experiments under influence of socio-economic situations of life or due to violence. All this determines the necessity of improvement of legal support of medicobiological experiments, especially in terms of guarantee, safeguarding and protection of rights of a human (an experimental subject), development of effective mechanism of the implementation of relevant legal norms regulating the exercise of medicobiological experiments on humans.

To be sure, the key problem of modern period of development of medicobiological experiments in Ukraine is the issue of compliance of legal regulations with needs of society; compliance of medical and biological sciences with the timely, complex and effective adjustment of such relations.

That is why, a key topic in modern conditions of development of society and state, medical and biological sciences is the research of issues of state regulation of medicobiological experiments with the aim to develop a common conceptual position on improving of the legislation of Ukraine in the context of maximizing ensurance, safeguarding and protection of the rights of individuals-patients.

Factors that determined the appearance of legal regulation of the use of medicobiological experiment on humans are complex, connected to the need to ensure individual rights and freedoms, aimed at preventing violations. In legal literature, such factors include, preeminently, the specific historical events that led to the need for «inclusion» of legal means to regulation of the relevant phenomena and processes of medical and biological nature. In particular, history has evidences of medicobiological experiments on humans that were horrific by content and results and were conducted by Japanese doctors on prisoners of 1939–1945; German doctors on Jews, Gypsies and prisoners from Soviet army during the World War II [2, 15].

There are well-known facts of medical experiments on humans in the early XXth century by Russian researchers [3, 11] and in the middle of the XXth century by American doctors [4, 9, 10]. All these experiments on humans were tragic and sparked considerable public outcry. These facts required an appropriate response from the side of the international community and introduction of appropriate legal regulation of biomedical experiments on humans in order to safeguard and protect human subjects.

Legal regulation of exercising of medicobiological experiments on humans is determined by: the regularities of medicine; the specifics of medical researches realization; the aim to protect the human-experimental subject and minimize the risk of negative consequences for their life and / or health.

The explanation of it is that each new medicine discovery signifies, if not life

saving, but at least facilitates serious illnesses for many people. However, studying of each new discovery at a certain stage of investigation there appears a need to check means or a method on the person, the results of action of which can not be predicted with certainty i.e. voluntarily expose a person or even a group of people with unknown, possibly dangerous medical means and methods on conditions of minimizing the risk of negative consequences. To get rid completely of the risk is not possible in such medical research. That is why the appearance of legal norms in the field of biomedical experiments is determined by the need for consistent protection of a human, on whom new methods or therapies are tested. Accordingly, it allows to reduce a risk and prove it, in order a person does not become an object of not prepared experiments or too long checking methods with more damaging consequences than it originally expected [5].

It should be admitted that in general legal regulation today is one that comes from the condition of medicobiological researches. Today, the medicine can not fully develop without searching of new treatments, diagnostics and prevention, which, in turn, is usually accompanied by the need for medical experiments. The task of legal regulation, the task of health law in general must be to create a clear, thoughtful, and detailed (in perspective with the legislative confirmation) conditions of legitimacy of such experiments realization [6, 345].

In other words, the development of medical science and practice inevitably linked to researches on humans. And such studies demand proper legal regulation. The awareness of this made the mankind to seek the line that separates «the criminal experimentation on humans» and the necessary research process, and such margin is established and guaranteed from the side of law [7].

It should be noted, that legal regulation of realization of medicobiological experiments on humans has objectively determined character associated with the level of development of society, health and life sciences, awareness of social importance and social danger of medicobiological experiments. Taking this into account, we consider it appropriate to generalize the system of factors that determined the creation and formation of legal regulation of realization of medicobiological experiments on humans, and today directly influence its development. They include:

- Legal factors, relating to the absence or imperfection of existing legal means to ensure the rights and freedoms of persons who are subjects of experiment; activation of legislative activities of the international community to ensure the rights and freedoms in the process of conducting of medicobiological experiments, to prevent violent involvement for the human in realization of medicobiological experiments;
- Humanistic factors related to awareness of the necessity of introduction or strengthen of safeguarding and protection of the rights and freedoms of persons who are subjects of experiment concerning the prevention of realization of medicobiological experiments against a human's will, the need of conditions of getting the absolute consent, preventing of undue risk to their life and health, and to their descendants; respect for human rights and freedoms in conducting of biomedical experiments; non-admission of repetition of mistakes in realization of medicobiological experiments, which caused damage to life or health of a human, that were in history;
- Scientific factors relating to enabling of development of medical and biological sciences, to provide growth of new knowledge and rethinking of existing, aimed at the establishment of patterns of various diseases, mechanisms of their development, elaboration and testing of the effectiveness

of new methods of prevention and treatment;

- Economic factors, which stipulate the need of invention of new means and methods of prevention and treatment, which in future will give the opportunity to save the health and lives of people, to make means and methods of treatment more economically accessible to people;
- Social factors, the content of which is the level and peculiarities of development of society that is aware of general social purpose of medicobiological experiments on humans, their level of danger, and the necessity of proper legal regulation of realization of medicobiological experiments.

Aforementioned factors determined the initiation of legal regulation of the realization of medicobiological experiments on humans, its formation and are subsequently determining the development of such regulation.

Within the legal science problems of legal regulation the implementation of conducting of medicobiological experiments on humans was singled out in the 30s of XXth century, which took place under the influence of medical experiments that were conducted during the World War I and the War of Japan and China, resulting in the harm of hundreds of thousands of people.

Such experiments were about endurance tests for the human body from the effects of temperature: development of methods of people's reanimation from the negative impact of temperature conditions; experiments during which the human-subjects were infected with sexually transmitted diseases, and who later became the object of research on the peculiarities of the diseases progression. But the most significant impact on the appearance of the first law acts in the sphere of legal regulation of medicobiological experiments was the Nuremberg trial on Nazi doctors. The horrors of medical experiments made by Nazi doctors on prisoners in concentration camps of Dachau, Auschwitz, Buchenwald and others were impressive with their cruelty, scope and absurdity. As a result, the problem of medicobiological experiments on humans was recognized as violating of personal rights and freedoms and is not only a medical, bioethical issue, but also an issue of international legal character. The danger of uncontrollable medicobiological experiments, their dehumanized nature was recognized. The preamble of the Judgement of the Nuremberg Tribunal [8] directly indicates that the severity of testimony that lie before us, makes us to conclude that some types of medical experiments on humans generally meet the ethical standards of the medical profession only if their conduct is limited with appropriate, clearly defined frames. Moreover, the document included the separate section — admissibility of medical experiments. The project of that element of the sentence was created by American medical experts — Leo Alexander and Andrew Ivy, who studied the medical experiments conducted by Nazi doctors and proposed principles of admissibility of medical experiments [9, 172].

Later the above-noted text would be known as the Nuremberg Code (hereinafter — the Code), which at the international legal level entrenched the law norms that regulated the requirements for conducting of medical experiments on a human. With the adoption of the mentioned Code the researches on problems of legal regulation of medical experiments on humans became more active. A special attention is given by the scholars to the principles embodied in the Code, namely absolute consent of a person to the experiment; orientation of the experiment towards socially positive results; avoidance of all excessive physical and mental suffering and injury; impermissibility of the experiment upon condition that *a priori* there are grounds to suspect the possibility of death or individual injuries of the subject; the degree of the risk associated with the experi-

ment must never exceed the humanitarian importance of the problem to be solved by this experiment etc. The above-noted international act actually comes out of the impressions that was made by medical researches during the World War II, and is aimed at enabling countermeasures against antihumanity of medicobiological experiments on humans. The Code actually formed the basis of legal regulation of medicobiological experiments on humans. In legal literature scholars unambiguously draw attention to the fundamental importance of the Code in the system of medical law sources, which recognized principles of medical experiments on humans. Scientists draw attention to the role and perspective of the provisions of the Code, its place in the process of establishing of legal regulation of medicobiological experiments [10].

The attention should also be paid to the provisions of the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10.12.1948. It does not contain the provisions regulating the conducting of medicobiological experiments, at the same time it enshrines fundamental human rights. According to Art. 1 all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood. In addition to that Art. 3 and 5 establishes that everyone has the right to life, liberty and security of person. No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. The realization of medicobiological experiments on humans is based on these rights and freedoms what is the foundation of humanity of experiments prohibition of violation of human rights and freedoms [11].

In the same context in the legal literature are analyzed the provisions of the Convention on Human Rights and Fundamental Freedoms of 04.11.1950 [12], which stipulates the prohibition of torture (Art. 3); the right to liberty and security (Art. 5); the right to an effective remedy (Art. 13) etc. [13].

Particular scientific interest to the problems of legal regulation of medicobiological experiments increases in the 60–70s of the XXth century. During this period the practical work in the sphere of medicobiological experiments became much more active, new medical technologies were arising and developing. As a result, in 1964 the European Social Charter was adopted, the provisions of which continued legal regulation of rights and freedoms. The content of the above-noted Charter did not directly stipulate the conditions and procedures of medicobiological experiments, at the same time the provisions dealing with the safeguarding and protection of human rights and freedoms were regulated there [14].

Significant importance in the system of medical law sources, especially concerning issues of medicobiological experiments, has the Declaration of Helsinki (Declaration of Helsinki of the World Medical Association «Ethical Principles for Medical Research Involving Human Subjects» from 06.01.1964) [15]. The World Medical Association developed the Declaration of Helsinki as a statement of ethical principles for medical researches involving human subjects, including researches on identifiable human material and data. Ethical principles enshrined in the Declaration of Helsinki, were the object of research of scientists in the field of law, and are an element in historiography of scientific regulation of realization of medicobiological experiments on humans.

Also the valuable importance in the system of medical law sources has the International Covenant on Civil and Political Rights [16], Art. 7 of which stipulates: no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation. In turn, the provisions of the International Covenant on Economic, Social and Cul-

tural Rights (ICESCR) [17], stipulates that the States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity (part 3 of Art. 15).

In 80–90s the problems of legal support of realization of medicobiological experiments were continued to be explored with renewed vigor that was connected with the intensification of researches in the sphere of medicine, focusing on humanities researches, and the development of legal regulation of medicobiological experiments on the legislative level of Ukraine.

During this period on the international level was adopted Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS-164) from 04.04.1997 [18], ratified by Ukraine in 2002 [19]. In the content of this Convention for the first time it was introduced the concept of professional standards, was stipulated that any intervention in the health sphere, including scientific researches, must be carried out in accordance with correspondent professional obligations and standards. The issues of consent on human medical experiments are the subject to above-noted Convention. It is also defined the conditions for the protection of persons who are not able to give such consent, is enshrined the provisions concerning the protection of persons suffering from mental disorders etc.

It should be noted that with the independence of Ukraine gave a start for developing of the national legislation of Ukraine in the health sector, which ensures the legal regulation of certain issues of medicobiological experiments on humans on the national level.

According to Art. 28 of the Constitution of Ukraine no one without their consent can be subjected to medical, scientific, or other experiments [20]. The Law of Ukraine «Fundamentals of the Legislation of Ukraine on Health Care» concedes the realization of medicobiological experiments on humans under conditions of: available socially useful purpose; scientific feasibility of medicobiological experiments; publicity of experiment application; the subject's full awareness of the impact of medicobiological experiment on the organism; exceeding of probability of success over the risk of causing serious consequences to the health or life of the subject; the subject's voluntary consent to the experiment; preservation of the necessary medical confidentiality [21].

In turn, the provisions of the Law of Ukraine «On Medicinal Products» stipulate the order of clinical testing of medicinal products that may be conducted only with the purpose of determination or confirmation of the efficacy and safety of medicinal product and only in specialized medical institutions after the mandatory assessment of ethical and moral and legal aspects of the program of clinical testing by ethics committees [22].

The beginning of the XXI century becomes decisive for the further implementation, and, the most important, improvement of the legal regulation of medicobiological experiments on humans. This is determined by a significant intensification of scientific researches in the sphere of medical experiments, the appearance and introduction of new nanotechnologies in medical practice that enhanced the problems of moral and ethical principles of intervention into the human's nature, their life and health.

Within bioethics the social mechanisms are being formatted. Such mechanisms provide the development of codes of ethics, laws, increasing of responsibilities of professionals — doctors and biologists, extension of their duties vested not only on personal, but also on the legal level. All nanobiotechnologies and nanomedicine, enriched by new experimental and clinical studies are the basis for their implementation to medical practice; they require mandatory moral, ethical, bioethical and legal qualification. As a result of discoveries and achievements

in molecular biology, genetics, nanomorphology, nanopharmacology, evolutionary biology the unprecedented opportunities to change human nature are opened. Many of these achievements aimed at human benefit, but there is also a danger to use them in another way [23].

During this period the issues of priority of ethical and moral principles in conducting of experimental medical activity with the impact on the human body become actual, because they have to be embodied in any scientific-research medical research experiment. In conformity with this, in S. Pustovit's opinion, two main mechanisms of ethical regulation of scientific projects are following: 1) the procedure for obtaining of informed consent of a subject; 2) the ethical (bioethical) examination of the project [24].

Special scientific attention is given to the complex of issues related to the definition of the new role and place of biomedical research and medicobiological experiments in modern legal, medical, genetic sciences and philosophy. Within stated scientists tries to consider the functional use of the medicobiological experiment through the prism of axiological and anthropological grounds and various methodological principles (transdisciplinary methodology) that navigate or pay attention of modern researcher to the issues of human vital activity in the context of cutting-edge biotechnologies and the necessity for moral and legal regulation biosafety of a human [25].

Prominent scientific attention is driven to the legal status and activity of the Commission (committee) on ethics. One of the important duties of the control of the compliance of the content of medicobiological experiments with the requirements for scientific researches is placed on them [26].

It should be noted that the year of 2000 was marked by the adoption of a number of legal regulations that specified the number of provisions of laws in the field of use of medicobiological experimentation. In particular, the Ministry of Health of Ukraine on 23.09.2009 adopted the Decree № 690 «The Procedure for Conducting Clinical Trials of Medicinal Products and Expert Evaluation of Materials Pertinent to Clinical Trials and Model Regulations of the Ethics Committee». It defined the basic requirements for conducting of clinical testing of medicinal products that may be held with the participation of patients (volunteers) by full or reduced program, including testing the bioavailability / bioequivalence as well as international multicenter clinical trials. The document identifies general principles of clinical trials, the basic requirements for the protection of subjects, evaluation of ethical, moral, legal aspects of the testing, and the procedure of its holding. Clinical testing conducted in healthcare facilities that have a license to practice medicine and a certificate of accreditation issued by the Ministry of Health or its authorized body [27].

Particularly crucial for the further development of medicobiological experiment on doctrinal and practical legal levels was the traditional Congress of Bioethics. Starting in 2000 and up to present there were only five scientific events involving leading experts in the spheres of medicine, law, philosophy etc., each them examined the complex key problematic issues related to the need to create an appropriate legal framework in the field of medical services, further development of studies of bioethical issues, introduction into a customary practice of the principles of bioethics, broadening of teaching of bioethics at school, creation of openness of academic and medical institutions, protecting of human rights and dignity in view of the current application of biologic and medical achievements.

The abovementioned facts give reasons to say that the problem of legal regulation of realization of biomedical experiments on humans reveals through the features of the condition and prospects of development of society. The development of medicine determines the

emergence of a significant number of varieties of medicobiological experiments on humans which needs the doctrinal classification and further legal distinction on the legislative level.

Therefore, the problem of the legal status of medicobiological experiment requires its thorough scientific investigation, identification of features of civil legal relations arising as a result of medicobiological experiments on humans.

Summarizing the abovementioned, the author maintains positions about the necessity of scientific rethinking of the characteristics of contractual regulation of relations in the application of medicobiological experiments on humans, in view of the peculiarities of modern medicine, international and national law norms. However, the absence of the unified science-based concept of reforming of the regulation of medicobiological experiments requires new unified doctrinal approaches to improving the legislation of Ukraine and brings it in accordance with international legal standards in health care. The development of medical practice requires the development trends and ways of further improving the medicobiological experiment as complex legal phenomenon. In conclusion, the author would also like to indicate the necessity of further comprehensive research of features of criminal and legal relations arising as a result of realization of medicobiological experiments on humans. ◆

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Nakaz MOZ Pro zatverdzhennya Poryadku provedennya klinichnykh vyprobuvan likarskykh zasobiv ta ekspertyzy materialiv klinichnykh vyprobuvan i Typovoho polozhennya pro komisiyi z pytan etyky, http://zakon4.rada.gov.ua/laws/show/z1010-09; Nakaz MOZ Typove polozhennya pro komisiyu z pytan etyky http://zakon4.rada.gov.ua/laws/show/z1462-12.

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Кашканова Н. Роль деонтологических норм в формировании законодательства, регулирующего порядок проведения медико-биологических исследований с участием человека. Статья посвящена проблематике правового регулирования медико-биологического эксперимента на людях. В частности автором рассматриваются факторы, обусловившие появление правового регулирования применения медико-биологического эксперимента на людях, имеющих сложный характер и связаных с необходимостью обеспечения личных прав и свобод человека, нацеленные на недопущение их нарушения. Отдельно автором анализируется, отечественное законодательство Украины в сфере здравоохранения, которое на национальном уровне обеспечивает правовое регулирование отдельных вопросов проведения медико-биологических экспериментов на людях. Автор делает выводы о необходимости научного переосмысления особенностей договорного регулирования отношений при использовании медико-биологических экспериментов на людях и подчеркивает необходимость выработки единых доктринальных подходов к совершенствованию законодательства Украины и приведения его в соответствие с международными правовыми стандартами в сфере здравоохранения. Вместе с тем, автор обращает также внимание на необходимость дальнейшего тщательного научного исследования особенности уго-

ловно-правовых отношений, возникающих в результате проведения таких экспериментов на людях.

Ключевые слова: права человека, биомедицинские исследования, клинические испытания, лекарственные средства, информированное согласие, зарождения и становления правового регулирования осуществления медико-биологического эксперимента на людях

Kashkanova N. The role of deontological norms in formation of legislation regulating the procedure of medical and biological research involving humans

This article is devoted to the problems of legal regulation of medical and biological experiments on humans. In particular, the author examined the factors determined the appearance of legal regulation of the use of medicobiological experiments on humans that have a complex nature and related to the need to ensure individual rights and freedoms, aimed at preventing violations. Separately, the author analyzed the national legislation of Ukraine in the health sector, which on the national level provides legal regulation of certain issues of medicobiological experiments on humans. The author made conclusions about the necessity of rethinking of the peculiarities of contractual regulation of relations in the application of medicobiological experiments on humans, and emphasized the need to develop a unified doctrinal approach to improving the legislation of Ukraine and bring it in accordance with international legal standards in health care. At the same time, the author also noted the need for further comprehensive scientific research of the features of criminal and legal relations arising as a result of such experiments on humans.

Keywords: human rights, biomedical research, clinical trials, medical products, informed consent, appearance and formation of legal regulation, realization of medical and biological experiments on humans