PRACA POGLĄDOWA
REVIEW ARTICLE

INTERNATIONAL LEGAL STANDARDS FOR CONDUCTING BIOMEDICAL EXPERIMENTS ON ANIMALS: STATUS AND PROSPECTS OF DEVELOPMENT

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Cruelty to animals can exist neither where people are truly educated, nor where true scholarship reigns.
Alexander Humbolt

ABSTRACT

Introduction: The article highlights the basic principles of the use of animals in biomedical research raised the main problems of vivisection. It also suggests specific steps to enhance the humanization of this process. The conclusions are the following: it is very important to prevent cruelty to animals in the context of resolving bioethical and legal problems associated with the implementation of the principle of humanism and the protection of animal rights. Modern science and the practice of preclinical and clinical tests should be involved into serious challenge in order to improve and universalize the process of medical and biological research technology in vitro.

The aim:: The purpose of the article is to study the main international legal principles of using animals in biomedical experiments, as well as to determine the main problems on this issue and to outline the ways to resolve them.

Materials and methods: The research material is a modern international regulatory framework that establishes the basic principles for the animals treatment. The methods of information retrieval, analysis, systematization, and generalization were used in this article.

Review: As it is well-known, human treatment of people begins with a human attitude towards animals. Nowadays the international community has adopted enough legal acts regulating the proper behavior with animals, including those specially cultivated for such studies (laboratory) when conducting biomedical experiments. Recently, both, in the national legislation of European countries and international legislation, there have been trends in the protection of both the general rights of animals as well as intensification of their protection in the field of biomedical research.

Conclusions: it is imperative, both at the international and national levels, to adopt programs for development and support of scientific study of the in vitro biosystems introduction into the practice of toxicological studies.

At the national level, it is necessary to criminalize the violation of international standards for conducting biomedical research using animals, strengthen other types of responsibility, and create a special system of state bodies responsible for the policy of using animals for biomedical purposes and exercising control in this area. Both, international and national legislation should impose a direct ban on the use of in vivo technologies in case of the possibility of using in vitro technologies.

KEY WORDS: vivisection, biomedical experiment, animals, legislation

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INTRODUCTION

Tests related to the use of animals as experimental material in biomedical research have always caused and continue to cause heated debates. Vivisection (from lat. vivus – living, and sectio a cutting) always had both, supporters and ardent opponents, because vivisection was vivo surgical manipulation with the purpose of studying the properties of pharmaceutical products, development of new methods of surgical, therapeutic, psychological treatment of various diseases., The conflict between them goes beyond the scientific debate very often. In addition, it moves into an active phase. The society becomes a witness against the trials and convictions in respect of both supporters and opponents of vivisection.

THE AIM

The purpose of the article is to study the main international legal principles of using animals in biomedical experiments, as well as to determine the main problems on this issue and to outline the ways to resolve them.

MATERIALS AND METHODS

The research material is a modern international regulatory framework that establishes the basic principles for the treatment of animals. The methods of information retrieval, analysis, systematization, and generalization were used in this research.

REVIEW AND DISCUSSION

There is no treatment for around half of all diseases in the world. It can take many years of painstaking work using a wide range of research techniques to understand how the body works, and how diseases are progressing, and to find cures, vaccines or treatments. There is overwhelming scientific consensus worldwide, where some researches, using animals is still essential for medical progress.[9]. Therefore, the need for regulation of biomedical research the procedure is undoubtful. Firstly, it is necessary for both, for creating new methods of treatment and creating new dosage forms. For example, it is impossible to create new dosage forms with their subsequent registration [10] without research. The issue of preventing the negative effects of individual biochemical compounds on human health and the environment is very important. [11] These are just some of the reasons for the necessity for researches on animals. As it is well-known, human treatment of people begins with a human attitude towards animals. Nowadays the international community has adopted enough legal acts regulating the proper behavior of humans with animals, including those specially cultivated for such studies (laboratory) when conducting biomedical experiments. The Regulation on the Use of Animals in Biomedical Research, adopted by the 41st World Medical Assembly in September 1989, occupies a rather important special place among them. The basic tenets of the provisions of this document of this Regulation determine the following principles for the use of animals when conducting biomedical research are prescribed: conducting training activities with the staff of research institutions on the proper handling, transportation and care of animals; provision of veterinary support for biomedical experiments; all research institutions must comply with the rules of humane treatment of laboratory animals [1].

The International Recommendations (Ethical Code) for conducting biomedical research and using animals, which were developed and published in 1985 by the Council of International Scientific Organizations, is an important document. The main ethical and legal provisions, enshrined in the recommendations, are as follows: in order to develop more advanced model of healthcare there should be used mathematical models, machine modeling and biological systems in vitro; experiments on animals should be carried out only after assessing their value for human health or the animals and exclusively for the development of biological knowledge, for experiments it is necessary to use only floor amount of healthy individuals; researchers should treat animals in such a manner as to minimize inconvenience, suffering and pain, including the use of proper sedatives, analgesic or narcotic drugs in accordance with the standards adopted in veterinary practice (if it is necessary, there can be a diversion protocol, the decisions are made the relevant competent committee); in challenging cases, animals that cannot be treated, are to be mortified in a painless way; laboratory animals should be provided with optimal living conditions and veterinary care; training on animal welfare for personnel, conducting research [2].

As it can be seen from the abovementioned, both documents imply the vital need for biomedical research with use of the animals. According to the first document, namely the Regulation on the use of animals in biomedical research, there is no alternatives to the research involving animals. The second document, namely the International Recommendations (Code of Ethics) for conducting biomedical research using animals, contains an alternative to experiments based on laboratory animals, which includes the use of mathematical models, machine modeling, and biological systems in vitro. Although, according to the above-mentioned International recommendations, such an alternative should be implemented in cases "where necessary" instead of "where possible". That is, according to the logic of the authors of this document, the alternative research methods with animals should be used only if a certain type of research cannot show the proper quality of the results without using alternative methods, and not in an exactly opposite situation, when applying the alternative methods ensures the proper quality of experiments. The latter method of application of the alternative methods could sharply reduce the need for laboratory animals' usage.

The European Convention for the Protection of Vertebrate Animals used for experiments or for other scientific purposes, adopted by the member states of the Council of Europe on 18th of March, in Strasbourg in 1986, establishes the following principles: animals which used for scientific purposes should be provided with proper care, veterinary support and conditions that allow them to meet their physiological and ethological needs; scientific experiments with animals should not be carried out only in case if there is a justified and feasible possibility of using another acceptable scientific method without using animals and states should encourage the use of such methods; if it is necessary to conduct scientific experiments with animals, there should be a careful approach to the selection of specific animals with the desired justification of such a choice by the competent state authority, there is a need for selection of the safest and least traumatic methods with the smallest number of animals tested and the most satisfactory results; widespread usage of methods of general or local anesthesia or methods of analgesia, if possible and appropriate; the most painful and traumatic research activities must be conducted only with the consent of the competent public authority; upon completion of any scientific procedure, the person responsible for this procedure or a veterinarian makes a decision on supporting or sustaining life of the animal or its mercy killing using the euthanasia method in case the animal constantly experiences pain or anxiety; no animal, after participating in an experiment that is grievous for its health, can take part in an experiment for the second time, except conducting procedures under anesthesia and subsequent killing, or if it implies minimal intervention; according to the decision of the competent state bodies, the animal may be released after experiments conducted on it, if the care provided by the researchers allows the animal to be in a normal physiological state, the release of the animal to freedom to achieve educational or training

purposes is not allowed; creation of a special permit system of state bodies that could issue the appropriate permissions to competent persons to conduct experiments with the participation of animals; breeding ground and supplying institutions, as well as user institutions must be registered with the appropriate state authority; animal welfare conditions must comply with international standards, including with appropriate labeling, registry maintenance and proper veterinary care; stray domestic animals cannot be used in research, animals originating only from breeding establishments or supplying institutions must be used for these purposes, if there is not any general or special exemptions; proper training of personnel, who conduct research using animals; conducting research with the use of animals for educational purposes for professional training of specialists may only take place under the supervision of a competent responsible person and only in cases where the purpose of such classes cannot be achieved by other methods (for example, using audiovisual media, etc.); states maintain special statistics on research, the data of which are transmitted to the Secretary General of the Council of Europe; states maintain special statistics on research, the data received is transmitted to the Secretary General of the Council of Europe; in order to avoid unnecessary repetition of research using animals, states recognize the results of such research conducted in other countries [3].

Recently, both, in the national legislation of European countries and international legislation, there have been trends in the protection of both the general rights of animals as well as intensification of their protection in the field of biomedical research.

For instance, in the countries of European Union there is an outright ban on testing of cosmetics on animals as well as it is prohibited to crop the tail, the ears and conduct onychectomy [4].

For the first time in the European region, at the constitutional level, Switzerland has secured the obligation to ensure animal welfare. In 1994, in Switzerland, there was a referendum, which changed the status of animals from "things" to "sentient" creatures. In Switzerland, the Law of 1978 regulated in detail the issues of ensuring the well-being and protection against ill-treatment of domestic animals as well as laboratory and agricultural ones. The law contains requirements for keeping animals, training personnel for working with laboratory animals, conditions for obtaining permits for keeping wild and domestic animals, animal trade, trade transportation. Special attention was paid to obtaining permission to conduct experiments, as well as the need for anesthetization of the animal during experiments.

In 2002, the Federal Republic of Germany completed the provisions of the Constitution on the protection of animals (Article 20a). Active work of public organizations (Tierschutzverein) - Animal Protection Society has led to concrete measures for the protection of animals. The Law on the protection of animals establishes penalties in case of violation of the rules for the treatment of animals, as well as a special taxation [5, p. 373]. In Germany, euthanasia of healthy animals is completely prohibited [4].

Spain is the world's first country that equalized human and animal rights. In 2008, it recognized the right of every great ape to life, freedom, and protection from cruelty. Nowadays in Spain, monkeys cannot be regarded as objects of private property, experiments on monkeys are prohibited, and their keeping in circus and television programs and living conditions in zoos have been significantly improved.

In April 2016, New Zealand officially recognized that all animals are intelligent creatures. Those people, who mistreated animals, are persecuted. Research and experiments on animals are prohibited.

India became the first country in the world, which has acknowledged the rights of dolphins. Dolphins should be understood as "personalities of non-human nature" with the right to be considered individuals. There is a prohibition against dolphinariums and dolphins' captive breeding stations. Furthermore, India became the first country in South Asia that issued a ban on testing cosmetics and its ingredients on animals [4].

The adoption of such humane laws was preceded by a series of scandals, the subject of which were cases of cruel treatment of animals during the conduct of biomedical experiments.

One of the most egregious cases of cruelty to animals took place at the Institute for the Behavioral Research in Silver Spring, Maryland, the USA in 1981.

A group of scientists led by Edward Taub conducted research on monkeys of the Philippines, the purpose of which was to study neuroplasticity. Its aim was to study the possibility of primate brain to change under the influence of experiments. Specifically, it was manifested in the form of removal of the spinal ganglion, and subsequent attempts to control the limbs of monkeys with an electric shock. The animal researcher Taub was charged with 17 sentences, because of the first trial in the history of the United States of America [6].

In Great Britain in 1997, the story of the bullying of the staff of the animal testing laboratory Huntingdon Life Sciences has a wide public response. The public was presented with a video in which the laboratories were puppies, imitated sexual intercourse with them during blood sampling for tests [7].

In 2002, the British Union for the Abolition of Vivisection published videotapes showing incidents of ill-treatment of experimental monkeys at the University of Cambridge.

In particular, images with animals were shown, in which cranial boxes were opened for the subsequent introduction of various toxins into the brain. Animals deliberately caused a stroke and left for a long time without any help. An interesting fact is that despite the enormous public response, the inspection of the university laboratory carried out by government representatives did not reveal any irregularities [8].

It should be noted that the authors of the article understand the need for appropriate biomedical experiments on animals. In some kind of researches there's simply no alternative options to exclude the use of animals in this matter. For example, such research can include the devel-

opment of new products aimed at the treatment of arthritis, which in turn implies a model that completely simulates the physiological characteristics of the human body. At the same time, searching for the ways to minimize the pain and physical suffering of animals must be continued and intensified.

CONCLUSIONS

As the results of the newest biomedical research show, the effectiveness of toxicological studies in biological systems in vitro is in most cases not inferior to the effectiveness of studies using experimental animals (in vivo). The serious task for improving and widespread introduction of technology into the process of biomedical research in vitro aiming to reduce the number of in vivo experiments in order to resolve bioethical and legal problems, associated with the implementation of the principle of humanism and the protection of animal's rights, preventing ill-treatment of them should be given. Modern science and the practice of preclinical and clinical researches must reduce the number of them to a possible minimum with the prospect of completely abandoning of researches using experimental animals, as well as legal regulation of the abovementioned processes in international law and national legislation of the countries of the world should be adopted immediately.

Nowadays, international acts with all their progressiveness and humanism, regulating animal rights in the process of carrying out biomedical research, must focus on the protection of the rights of laboratory animals. A number of shortcomings characterize them, so they must resolve the following provisions: they cannot be legally binding, as they are not accepted by states, but by international organizations (for example, as the Regulation on the Use of Animals in Biomedical Research, International Recommendations for Conducting Biomedical Research with the Use of Animals); there is no international legal act that would apply to countries all over the world, at the UN level with novative achievements of medical and biological science; there is no international competent authority whose task would be to control the use of animals in biomedical experiments; there is no Unified register of biomedical research with the participation of animals in order to avoid inappropriate repetitions.

In addition, it is imperative, both at the international and national levels, to adopt programs for the development and support of scientific researches to study the introduction of in vitro biosystems into the practice of toxicological studies.

At the national level, it is necessary to criminalize the violation of international standards for conducting biomedical research using animals, strengthen other types of liability, and create a special system of state bodies responsible for the policy of using animals for biomedical purposes and exercising control in this area. Both, international and national legislation should impose a direct ban on the use of in vivo technologies in case of the possibility of using in vitro technologies.

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