Research article
DOI: https://doi.org/10.21202/jdtl.2023.4

Medical Nanorobots in the Focus of Law

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Keywords

Digital technologies,
ethics,
healthcare,
in vivo,
Isaac Azimov,
law,
medical robot,
medicine,
nanorobot,
regulation,
robotics

Abstract

Objective: to form doctrinal bases and mechanics of legal regulation of using medical nanorobots; to conceptualize the idea of nanorobotics law within the frameworks of its basic definitions, safety norms, risks, typology of devices, and legal parameters of technological terminology.

Methods: the cognition tools are represented in the form of integration between general scientific and modern special legal methods (including the methods of comparative legal studies, legal modeling and juridical forecasting, NBICS-convergence), which, taken as a whole, allow distinguishing in the study object not only juridical proper, but also anthropological, biomedical, informational, and mechanistic research projections.

Results: the author's definition of the medical nanorobot concept was formulated; the legal content and quasi-legal aspects of the definition that are important for the theoretical and applied development of terminology were investigated; the signs of related concepts (biomedical robot, nanorobotic system, medical nanorobotic system) were identified and logical connections between them were established; the classification of the main types of risks associated with the practical use of medical nanorobots was carried out; the list of theoretical and legal contradictions that are potentially capable of negatively affecting the future development of regulatory practice was revealed; the Russian and foreign experience of legal regulation and doctrinal understanding of the problems of medical nanorobotics (by the examples of the USA, Japan, Europe, China) was considered.

Scientific novelty: under the lack of interdisciplinary research, an attempt was made to comprehensively consider the concept of a medical nanorobot in a technological, legal and communicative way ("human robot" on a nanoscale) based on the advanced scientific research that defines the foundations of the future nanorobotic law. It is recommended to supplement the synergetic development of biomedical and related technologies, reflected in the models of robot law and robot ethics, with relatively independent concepts of nanorobot law and nanorobot ethics.

Practical significance: based on the analysis of the legal regulation system in force in Russia and abroad, mechanisms for improving domestic legislation were identified, including taking into account the achievements of juridical crowdsourcing. Within the framework of socio-humanitarian issues, a contribution to the development of legal, sociological, and psychological science is formed. A scientific and methodological basis was prepared for further legal research and law-making activities in the field of medical nanorobotics.

For citation

Gulyaeva, P. S. (2023). Medical nanorobots in the focus of law. *Journal of Digital Technologies and Law*, *1*(1), 89–122. https://doi.org/10.21202/jdtl.2023.4

Contents

Introduction

As a result of the evolution of socio-economic sphere, five technological paradigms were formed: the first industrial revolution, the epochs of steam, steel, oil and telecommunications. In the 2000s, researchers stated that humanity is on the threshold of the next, sixth nanotechnological paradigm. Futurologists predict the formation of the era of metacognitive technologies by the middle of the 21st century, the basis for which will be qualitatively new approaches to the perception of information (Yuan et al., 2020; Xue, 2022). The sixth nanotechnological paradigm is characterized by the convergence of complex self-organizing nano-, bio-, and information technology complexes that generate increased interaction between the anthropological and technological environment (Aseeva, 2017; Pashentsev et al., 2021). Nanorobots used in medicine are a special area for socio-humanitarian and legal research. Technologies that do not fully comply with the laws of the macrocosm (the laws of classical physics) and are used inside a human body are of interest to researchers, including in terms of ethical aspects and legal risks[1].

Within the research framework, basic concepts and general approaches to understanding medical nanorobototechnical law were developed, including the study of theoretical-legal problems and the classification of risks. The work provides recommendations on amendments to the Russian legislation.

The article provides a comparative-legal analysis of regulatory and general theoretical models; in particular, the experience of Russia, China, the USA, Japan and the European Union is studied. Russian and foreign developments serve as the basis for recommendations on the development of the theory and practice of Russian legal regulation.

The legal focus of the study reveals the technological essence of the phenomenon of medical nanorobotics. In particular, complex interdisciplinary approaches to the content of a medical nanorobot concept are proposed, based on Isaac Asimov's three laws: the priority of human life and health over the interests of a machine, the duty of the device to take care of self-preservation and subordination to people (subject to the first and second rules).

After the study of the problems of the conceptual and categorical framework, distinctions were made and the notions of "biomedical robot", "nanorobototechnical system" and "medical nanorobot" were defined.

The article identifies the fundamental problems that hinder the development of the regulation principles of medical nanorobotics: the issue of determining the legal nature of nanorobots, terminological and tort problems.

The legal and non-legal risks associated with the future regulation of the use of medical nanorobots in clinical practice were classified. Besides legal uncertainty, communicative-ethical and communicative-methodological risks, as well as risks in the field of information and technological security, were highlighted.

[1] Fosch-Villaronga, E., & Drukarch, Y. (2021, May). *On healthcare robots*. eLaw Center for Law and Digital Technologies. Leiden University, the Netherlands. https://arxiv.org/ftp/arxiv/papers/2106/2106.03468.pdf

The author proposes amendments and additions to the provisions of paragraph 3 of Article 34 of Federal Law no. 323-FZ of November 21, 2011 "On the principles of protecting the health of citizens in the Russian Federation", to Article 2 of the "Procedure for organizing the provision of high-tech medical care using a unified state information system in the field of healthcare", approved by order of the Ministry of Health of the Russian Federation of October 2, 2019 no. 824n "On approval of the procedure for the provision of high-tech medical care using the Unified state health information system", to Article 3 of the "Regulations on the organization of the provision of specialized, including high-tech, medical care", approved by the order of the Ministry of Health of the Russian Federation of December 2, 2014 no. 796n "On approval of the regulations on the organization of the provision of specialized, including high-tech, medical care", clause 6.1 to the "Nomenclature classification of medical items by types", approved by Order of the Ministry of Health of the Russian Federation of June 6, 2012 no. 4n "On approval of the nomenclature classification of medical items".

Methodological recommendations on the development of legislation in accordance with the hierarchy of regulatory-legal acts were prepared.

From the point of view of the evolution of law, the so-called technological imperative (Khabriyeva & Chernogor, 2020) serves as a catalyst for the transformation of basic concepts in jurisprudence, including methodological approaches. The latest developments integrate natural-scientific, technical, informational, philosophical, and legal aspects. Under progressive interdisciplinarity, supra-branch methods of NBICS (nano-, bio-, info- and cognitive sciences, as well as socio-humanitarian fields) are becoming particularly relevant (Zholobova & Schastlivceva, 2020; Jamali, 2018; Sweeney, 2020).

The empirical basis of the article is foreign scientific works devoted to research in the fields of nanorobotics, robotics, and nanotechnology. The references also include materials on the problems of classical physics, biophysics, medicine, optics, microfluidics, microbiology. Such a selection of sources is due to the need to fill in the gaps in both legal and general scientific terminology. The definition of nanorobot and medical nanorobot is innovative, especially for the humanitarian and legal sphere of the Russian science. The integrated approach allowed considering the technological nature of nanorobototechnical systems in the legal dimension. The interdisciplinary nature of the research object determined the choice of convergent technologies as a methodological basis.

1. Medical robots at the macro-, micro- and nanoscale: brief review of technological solutions

Medical robots have become the basis of breakthrough achievements in clinical medicine in recent decades (Fukuda et al., 2010). New technologies make it possible to compare information about patients (results of laboratory tests, diagnostic studies, including images, visualization) (Fortunato et al., 2010) and generalized information (anatomical atlases, statistics). The range of medical tasks of such devices includes surgical interventions, rehabilitation, and assistance to people with disabilities in everyday life (Wenyan et al., 2022). Such manipulations can be carried out by macroscale medical robotics, for example, produced by a well-known Da Vinci company (Min Sun et al., 2022; Rong Liu et al., 2022). Robots are also used in performing surgical operations per se, increasing accuracy, dexterity, reducing the factor of surgeons' hands trembling and providing the possibility of manipulating hard-to-reach areas (Jamali, 2018; Norasi, 2022). Robots significantly reduce injuries during surgery, save patients' regeneration resources and improve the prognosis of recovery. In order to rehabilitate postoperative patients or those suffering from extensive disorders, robotic devices were developed to restore the functionality of patients with musculoskeletal problems. A promising direction in medicine is "soft" robotics, which is associated with biocompatible materials and the ability of mechanisms to biomimicry. These are the devices made of materials similar to the tissues of living organisms and safe to work in direct contact with humans (Suulker et al., 2022; Bartkowski et al., 2022).

The above listed achievements in the field of of macroscale medical equipment development show the impact of robotics on clinical medicine and healthcare. In such conditions, it is assumed that reducing the size of medical robots will allow achieving qualitatively new results and provide discoveries both in clinical practice and biomedicine.

To illustrate the achievements of world science, we propose to consider several projects in the field of medical nanorobotics.

The Cyberplasm nanorobot, developed by a team of physicians, biologists and engineers, is designed on the model of a sea lamprey and, circulating in blood, performs diagnostic tasks. The device acts on the energy of glucose in the bloodstream[2].

The Bacteriorobot project is able to independently identify malignant tumors and contributes to the effective fight against them. Experts have genetically modified salmonella bacteria that are attracted to cancer cells due to the substance they secrete. Microscopic robots located in the bacteria automatically inject a medication. The medication is delivered directly to the tumor, avoiding healthy cells[3].

The researchers also developed (Marks & Cyr, 2018):

– a mechanical platelet to form blood clots in patients with clotting disorders;

– a nanorobot for detecting blood clots;

– a nano-knife for performing surgical interventions on individual neurons;

– a transport nanorobot made on the basis of deoxyribonucleic acid[4] and capable of delivering a useful substances to target cells.

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2 Poyezzhayeva, E. V. (2020). *Artificial intelligence in the theory of mechanisms and robotics*: tutorial. In 3 parts. Part I. Perm: Perm National Research-Polytechnic University Publ.

3 *Kriorus*. https://kriorus.ru/news/Yuzhnokoreyskim-uchenym-udalos-ispolzovat-nanoroboty-v-medicine

4 Deoxyribonucleic acid (DNA) is a macromolecule that provides storage and transmission of information from one generation to another and the implementation of a genetic program for the development and functioning of living organisms. The DNA molecule stores biological information in the form of a genetic code consisting of a sequence of nucleotides.

Until recently, one of the main challenges in the development of nanorobots was the problem of creating nanoengines, namely an energy-efficient power source for a device. In 2020, scientists approached the minimum size by creating a nanoengine with a diameter about 100 thousand times smaller than a human hair, which consists of only 16 atoms and is by far the smallest in the world. The engine is capable of rotating in the set direction. The invention makes it possible to collect energy at the atomic level, for example, scattered heat, in order to then convert it into mechanical motion, which can be used for various purposes, including medical ones[5].

It is important to note that the field of medical nanorobotics, although innovative, has long gone beyond the limits of foresight discussion: prototypes and serial devices are being tested by patients all over the world. Despite the presence of some lag in the development of technologies in our country, it is likely that similar projects will appear in Russia in the near future; also, it is possible to use foreign-made samples.

2. Types of nanorobots: communications of a human and a robot in the in vivo format

The scientific terms "in vivo" and "ex vivo" are literally translated from Latin as "inside a living organism" and "outside a living organism". High-tech medicine provides for more and more atraumatic "in vivo" targeted techniques that exclude damage to healthy organs, tissues and even cells.

According to Federal Law no. 323-FZ of November 21, 2011 "On the principles of protecting the health of citizens in the Russian Federation"[6], high-tech assistance is provided in the form of cellular technologies, genetic engineering, tools using robotic technology (Article 34, paragraph 3).

Doctors confirm that the functionality of micro- and nanorobots is applicable for various biomedical and medical devices, including for the purposes of cellular manipulation and imitation of biosignals, targeted delivery of medications, minimally invasive surgery, medical diagnostics, detoxification (J. Li et al., 2017). Microrobots are used on a scale from individual molecules to systems and organs of a human body. The devices are capable of probing ions and small molecules, including proteins. Tweezer nanomanipulators are suitable for processing biological samples ranging in size from a few nanometers (for example, proteins) to tens of micrometers (for example, cells). After the introduction of nanorobots into a blood vessel, such devices carrying the substance molecules move to the affected areas in the body, and then release the medication. Nanoengines can not only probe individual cells, but also pass through biofluids in the gastrointestinal tract to perform spot surgery (M. Li et al., 2021).

5 *A nanoengine is created that consists of only 16 atoms and operates at the boundary between classical physics and quantum mechanics*. https://www.atomic-energy.ru/news/2020/06/30/104950

6 On the principles of protecting the health of citizens in the Russian Federation. No. 323-FZ. (2011). *Collection of legislation of the Russian Federation*, 48, Article 6724.

Researchers assume that to date there are no standard definitions of the terms "microrobot" and "nanorobot", but there is an opinion that a more general term "microrobot" includes all related concepts and characterizes devices with a size of 1 nanometer (the diameter of an average atom is approximately 0.1 nanometers) (Diller & Sitti, 2013).

In modern literature, nano-robotic technical systems are understood as groups of devices designated as nanorobots and nanomanipulators (Khabriyeva & Chernogor, 2020).

2.1. Nanorobots

A group of nanorobots includes the following types of devices:

– molecular devices 1 to 20 nanometers in size, capable of performing mechanical movements under the impact of external stimuli;

– nanoengines ranging in size from 10 nanometers to 10 μ-meters, capable of using light, chemical, magnetic, ultrasonic, electrical and other energy from the environment;

– nanorobots using the technology of the so-called DNA origami, 5 to 100 nanometers long, suitable for transporting medications, capable of molecular recognition.

2.1.1. Molecular devices

Molecular devices can function due to the interaction of individual molecules with a size of a little more or less than a nanometer. The natural prototype of molecular devices is, for example, the ATP molecule (adenosine triphosphate)[7]. Scientists admit that artificial molecules do not replace natural ones, but help to carry out the desired manipulations with them. Molecular devices may work in lipid layers transferring ions and explore the intracellular space by passing through cell membranes. A nanorobot is kept at a distance from the surface by means of its chemical properties and is able to move autonomously, being launched by the energy of oxidation-reduction processes, light and heat (Erbas-Cakmak et al., 2015; Chen et al., 2018).

2.1.2. Nanoengines

Nanoengines are nanoscale devices designed to perform certain mechanical movements (e.g., rotation, rocking, displacement, delivery, compression) in response to certain stimuli (Guix et al., 2014). Various types of such devices are widely used to simulate biosignals, deliver medications, perform diagnostics, and isolate cancer cells (Wang & Pumera, 2015). The main classification of nanoengines is their division into fuel and fuel-free mechanisms.

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7 Adenosine triphosphate, or adenosinetriphosphoric acid, is a universal source of energy for all biochemical processes occurring in living organisms.

In 2015, a magnetic-acoustic hybrid fuel-free nanoengine[8] was developed, which consists of a magnetic nanospring and a nanodevice and is capable of using the energy of a magnet or ultrasound. The development of mechanisms capable of operating in a fuel-free mode is a promising area of scientific research; in particular, there is growing interest in using external fields, such as magnetic, electric, acoustic or light, to drive nano- or micro-devices (Villa & Pumera, 2019). Considerable efforts were made to create chemical-driven engines based on the surface catalytic decomposition of fuel contained in a solution of hydrogen peroxide. Special attention was paid to catalytic nanowire and microtube engines. Such devices are based on the driving force of oxygen bubbles and have a relatively high power required to perform various biomedical tasks (Wang & Wei, 2012).

2.1.3. DNA-nanorobots

DNA nanorobots are often referred to as a subgroup of nanoengines that function "based on the DNA principles". In fact, the technique of the so-called DNA origami was created in 2006 and is a technology designed on the basis of a natural prototype of deoxyribonucleic acid. Such a device uses programmed combinations of hundreds of short complementary oligonucleotides[9]. The fragments are folded by means of precise 2D and 3D shapes into a large single strand of "framework" DNA, stabilized by thousands of base pairs. DNA origami allows the self-assembly of discrete objects from the bottom up with subnanometric accurate characteristics (sizes from nanometer to micrometer and the mass of molecules up to gigadalton scale). A wide range of functional static nanostructures and dynamic nanodevices was constructed using DNA origami method (Rothemund, 2006).

2.2. Nanomanipulators

Nanomanipulators are larger in size compared to the group of nanorobots and are presented in the form of:

– nanomanipulators equipped with optical, magnetic or acoustic tweezers, similar to an end effector[10], which carry out non-contact processing of biological samples at the nanoscale;

– nanomanipulators equipped with atomic microscopy functionality that manipulate biological samples in air, liquid and other media, simulating an end effector using a nanoscale tip;

– nanomanipulators using electron microscopy, which perform on the basis of electronic visualization.

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8 *A fuel-free nanoengine is designed*. (2015, June 30). https://www.the-submarine.ru/news/1653

9 An oligonucleotide is a short fragment of DNA or RNA (ribonucleic acid) obtained by chemical synthesis or splitting of longer polynucleotides.

10 In molecular biology and biochemistry, the term "effector" or "effector molecule" is usually understood as a small non-protein molecule that selectively binds to certain proteins and regulates their biological activity.

2.2.1. Nanomanipulators with optical, magnetic or acoustic tweezers

Nanomanipulators with optical, magnetic or acoustic tweezers allow for precise actions with biological samples. For example, optical tweezers are instruments based on a tightly focused laser beam that is able to capture and manipulate a wide range of particles in its focal spot. Since its invention in 1970, optical tweezers have been widely used in such scientific fields as atomic physics, optics and biological sciences. Using a highly focused beam of light, optical tweezers can function as special end effectors of robots for capture and non-contact movement of objects ranging in size from tens of nanometers to tens of micrometers. Recent studies have demonstrated the capabilities of a robotic optical tweezer system for in vivo manipulations with individual cells in a bloodstream (X. Li et al., 2017).

In addition to cells, optical tweezers are able to manipulate individual molecules, such as proteins and nucleic acids[11], which makes it possible to achieve significant success in the study of structural dynamics and information about molecules. A molecule is attached to an optically trapped ball, while the free end of the molecule is attached to another ball, which is held in an independent optical trap. The movement of the optically trapped ball leads to stretching or relaxation of the molecule. Such studies provide new insights into various molecular and cellular changes: for example, hormone binding and receptor activation, molecular mechanisms and engines, tension of plasma membranes[12] in cells (Gardini et al., 2018).

Nanomanipulators with magnetic and acoustic tweezers are the area of scientific research in the field of classical physics, biophysics, optics, microfluidics, microbiology (Wang et al., 2022; Kuijpers et al., 2022; Jingui et al., 2020). Magnetic tweezers in molecular biology are considered to be analogous to optical tweezers and are a device capable of manipulating conditionally heavy samples if they are in close proximity to a magnet (Neuman & Nagy, 2008). Today, magnetic tweezers are used for biological detection and targeted delivery due to their unique characteristics of movement, the ability to penetrate biological tissues without harm to the body, and the possibility of wireless remote control (Deng et al., 2023). With the help of acoustic tweezers, three-dimensional acoustic manipulation of samples on a scale from a millimeter to a nanometer is possible. Acoustic tweezers are an innovative technology based on using acoustic radiation generated by ultrasonic waves (Qi et al., 2021).

[11] Nucleic acid is a high–molecular organic compound, a biopolymer formed by nucleotide residues. DNA and RNA nucleic acids are present in the cells of all living organisms and perform the most important functions of storing, transmitting and implementing hereditary information.

[12] Plasma membrane (cell membrane, cytolemma, plasmalemma) is an elastic molecular structure consisting of proteins and lipids.

2.2.2. Nanomanipulators based on atomic microscopy

Nanomanipulators based on atomic microscopy provide a new way of processing biological samples examined under physiological conditions (for example, in liquids). The achievements of the recent decade have shown that such a nanomanipulator is capable of examining the behavior of individual cells and molecules in a clinical setting. The integration of atomic microscopy with robotics makes it possible to create a nanorobototechnical manipulator that can process nanoobjects, opening up new opportunities for biomedical applications. Based on such microscopy using augmented reality and the tactile and visual feedback methods, an operator can control a nanoprobe. The robotic end effector allows performing operations with nanoobjects using a joystick, accurately determining the position of the probe tip. The devices can perform mechanical manipulations: pushing, cutting, deformation, touching (M. Li et al., 2019).

In combination with microfluidics[13], this procedure allows the probe to deliver medications to individual cells and manipulate them using microchannel cantilevers with nanoscale holes (Guillaume-Gentil et al., 2014), as well as to perform electrical measurements and analysis of ions and biomolecules (Aramesh et al., 2019). To probe a cell using a nanomanipulator based on atomic microscopy, it is necessary to immobilize cells.

2.2.3. Nanomanipulators based on electronic microscopy

Nanomanipulators based on electron microscopy open up new possibilities for robotic nanomanipulations. The electron microscope system includes a manipulator as a device, several microscopes ("eyes"), various end effectors, including consoles and tweezers ("fingers"), and various types of sensors.

A standard electron microscope is characterized by a low image processing speed and a small scanning area, while the throughput is limited (Shi et al, 2016). Besides, dynamic processes between the tip and nanoobjects cannot be directly visualized. The combination of robotics with an electron microscope provides a new type of nanomanipulator, which ensures accurate and fast visualization and nanomanipulation. Such systems include scanning electron microscopic nanomaterial, transmission electron microscopic nanomaterial, and scanning electron microscopy of the environment. The nanomanipulator allows influencing individual biological cells and is able to work in a gaseous environment, enabling to perform morphological visualization of biological samples containing moisture (Muscariello et al., 2005).

[13] Microfluidics is an interdisciplinary science describing the behavior of small volumes and flows of liquids.

2.3. Legal construct in communication of a human and a robot at a cell level

In scientific research, the technological context in understanding the nature of nanorobots often prevails over legal and humanitarian aspects; for this reason, it is especially important to identify legal aspects in the content of an innovative object. The legal essence of medical nanorobotics is revealed through the study of the specifics of public relations arising from the practice of using devices. These social relations are determined by the following factors:

– purpose of devices (therapeutic, diagnostic, surgical);

– the subject composition of participants in the development, maintenance and application of the device (medical personnel and specialists with technical competencies, employees of medical institutions or organizations engaged in the production and maintenance of technological devices);

– functionality of medical nanorobots (passing through environments, including barriers, transportation and release of medications, targeting, imitation or, conversely, removal of fragments, for example, platelets, manipulation of biological samples, detoxification, internalization, etc.);

– the quality of the device autonomy (whether it is controlled directly by medical personnel using a joystick or external radiation, works on the basis of a built-in program or is guided by individual physiological indicators of a patient).

A variety of possibilities and special conditions for the use of medical nanorobots determine the complex nature of public relations. The interaction between a robot and a human in vivo is at stake. The issues of communication between a nanorobot and a patient, a nanorobot and a doctor, a nanorobot and a technical specialist, as well as the distribution of responsibility between them are the most important area of regulation. Significant are the problems associated with the use of nanodevices without the will of a human, as well as under possible religious and ethical restrictions on the part of a patient or their relatives.

3. Three laws of nanorobotics

The modern scientific literature devoted to the study of the role and place of digital innovations in social reality is characterized by a combination of humanitarian and technological approaches. For example, a Chinese study reflects the methodology of complex perception of the phenomenon of microscopic biomedical devices based on the three laws of robotics by Isaac Asimov (T. Li, 2022). We propose to investigate this model in the context of nanorobotics.

3.1. First law of nanorobotics

The first law of robotics reads: “A robot may not harm a person” (Azimov, 1942). At the scale of nanodevices operating in vivo, this indicates the need to ensure the biocompatibility of materials, which can be divided into a biological reaction and a material reaction.

The biological reaction includes the reaction of blood, immunity and tissues that occurs during the interaction of the robot with the environment. The reaction of the material refers to changes in the physical and chemical properties of the device after it gets into a human body. According to research, the biocompatible material is the respective organic molecules and polymers with modules and structures close to real biological cells and tissues. The biocompatibility of materials takes into account such characteristics as immunogenicity, toxicity of substances used for the manufacture and waste products of the device, the effect of the nanodevice radiation on cells and tissues. At the present stage, there is a significant amount of research on biocompatibility, and the use of such materials in biomedicine in the development of in vivo techniques is an innovative area of scientific knowledge (Naidoo, 2021).

In the context of ensuring human security against threats to life or health, as well as legal risks associated with the violation of their rights, significant is the issue of replication of microdevices placed inside a patient's body.

3.2. Second law of nanorobotics

The second law of robotics, formulated for nanobiomedicine, implies that "a nanorobot must maintain its own existence as long as its self-defense does not contradict the first law" (Azimov, 1942), which indicates the need to evade everything that will lead to a loss of activity until the medical task is completed.

A good example is provided in a Chinese study of an antitumor nanorobot, which under normal conditions must go through four stages to penetrate tumor cells (intravenous injection into the bloodstream, accumulation at the site of the tumor due to infiltration, retention or targeting effect, penetration into tumor tissue, internalization[14]) (Xu et al., 2017). Researchers note that at the first stage, nanorobots injected intravenously must have good dispersion in order to maintain the ability to circulate in blood for a long time. However, when the devices enter the bloodstream, their surface is quickly covered with protein molecules, forming a "protein crown" (Wan et al., 2021). Obviously, the protein crown will change the size, stability and surface properties of nanorobots, thus affecting their targeting ability, cellular uptake, intracellular transport, pharmacokinetics[15], biological distribution and toxicity. Nanorobots can also be captured by immune cells in the circulatory system, tissues and organs. Obstacles include biological barriers, such as the blood-brain barrier[16], which complicates the delivery of some types of nanorobots.

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[14] Internalization (in the context of medicine) is the immersion of molecules into a cell.

[15] Pharmacokinetics is a branch of pharmacology that studies the kinetic patterns of chemical and biological processes occurring with a medication in an animal or human body.

[16] The blood-brain barrier is involved in maintaining the brain's self-regulation systems, protects the nervous tissue from microorganisms and toxins circulating in the blood, and various factors of the immune system that perceive the brain tissue as foreign. The blood-brain barrier performs the function of a highly selective filter through which nutrients and bioactive substances enter the brain from the arterial bed and the waste products of the nervous tissue are removed.

3.3. Third law of nanorobotics

Isaac Asimov's third law in the dimension of nanodevices is that "a nanorobot must obey orders given by people, or through actions not to allow harm to a human, except in cases where such orders or actions contradict the first or second law" (Azimov, 1942). This means that the controllability of nanorobots includes not only the direction and trajectory of the autonomous movement of the device, but also the number of medications loaded and the mode of delayed release of the substance.

Quite a large number of ways of targeting the device have been developed, for example, a vector field can be created in a physiological environment using an external signal. Then a robot will receive a directed driving force from the outside in order to move controllably. At the same time, nanorobots remain vulnerable to the interference of random Brownian motion (You et al., 2018).

Some studies have developed chemotactic[17] devices capable of "targeting" depending on the concentration gradient of glucose, reactive oxygen intermediates and inflammatory factors in physiological lesions (Ji et al., 2019).

Despite a large choice of targeting methods, it is impossible to foresee all the individual reactions of a human body during medical procedures; for example, there are obvious differences in chemical recognition strategies, i.e. the levels of receptor expression on the surface of affected cells vary from one individual to another depending on the type of disease and pathological condition (Taherkhani et al., 2014).

4. Medical nanorobotics: regulatory approaches

The problem of using medical nanorobots is a relevant and disputable topic characterized by a high pace of technical solutions updating. To prevent legal and administrative vacuum, it is proposed to formulate the general characteristics of contemporary regulation systems in this sphere:

– the absence of a specialized federal executive body to perform the functions of elaborating and implementing state policy, normative-legal regulation, control and supervision in the sphere of circulation and use of medical nanorobots;

– the interdepartmental nature of the initiatives and proposals of the working groups responsible for developing conceptual solutions in the field under consideration;

– the regulation by substatutory or soft-legal acts;

– the application of general norms of federal legislation on healthcare, such as norms on medical devices;

– the problems with legal methods, for example, the absence of a full-fledged conceptual and categorical apparatus in the field of medical nanorobotics.

[17] Chemotaxis is the motor reaction of microorganisms to a chemical stimulus.

At the initial stage, the international agenda was represented by the activities of the United Nations institutions (further – UNO) and reflected in the UNESCO report of 2008 “Nanotechnologies and ethics: policies and actions”[18]; the document formulates the role and significance of nanotechnologies for the world and UNO, presents ethical, legal and political aspects of development and application of innovations, prospects and risks for the society, science, and environment[19].

An example of foreign regulatory practice and technology policy is the successful experience of the United States of America (further – USA). In 2000, it launched a National Nanotechnology Initiative[20], who became the coordinator of more than 20 government departments and agencies working on various projects in this sphere. At that, regulation is not carried out by a special body, but mainly by two agencies: the US Food and Drug Administration (further – FDA), which approves a list of medical items, and the US Patent and Trademark Office. Under the auspices of the FDA, a Task Force on Nanotechnology was established in 2006, which initiated the development of a mechanism for regulating nanorobots and related technologies. In December 2017, a respective draft guide was issued by the FDA Center for Drug Evaluation and Research and the Center for Biological Evaluation and Research, which is presumably applicable for the regulation of nanorobots. The project includes regulations concerning drugs and biological products containing nanomaterials. The document notes uncertainty as to whether and to what extent these norms are applicable to nanorobots. The project reflects, in particular, how nanomaterials can be handled when developing new medications. At the same time, the FDA documents contain no established definitions of the terms “nanorobots”, “nanotechnology”, and “nanomaterial” (Norasi et al., 2022).

The European model of robotics regulation, which became known all over the world due to the succinct concept of RoboLaw[21], contains the norms about robots that help the elderly and sick in rehabilitation and improving the quality of life, as well as about devices aimed at restoring and compensating the work of human organs and tissues, including those “worn on the body and implantable”[22].

In the People’s Republic of China, the model of robotics regulation is stipulated in such documents as the Global State Development Program “Made in China 2025”[23] and the Plan

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18 *Nanotechnologies and ethics: policies and actions*. (2008). https://unesdoc.unesco.org/ark:/48223/pf0000152146_rus

19 UNESCO. *The ethics and politics of nanotechnologies*. (2006). https://kelty.org/or/papers/Kelty_UNESCO_Ethics_PoliticsofNano_2006.pdf

20 *National Nanotechnology Initiative*. (2000). https://www.nano.gov

21 *RoboLaw. Regulating Emerging Robotic Technologies in Europe*: Robotics facing Law and Ethics. https://www.robolaw.eu/projectdetails.htm

22 Civil Law Rules on Robotics European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). Resolution 2015/2103 (INL) of the European Parliament of 16 February 2017. https://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.pdf

23 *Made in China 2025: The Plan to Dominate Manufacturing and High-Tech Industries*. (2022, June 22). https://www.fdichina.com/blog/made-in-china-2025-plan-to-dominate-manufacturing/

for the Development of the robotics industry. At the same time, there is no full-fledged law on robots or another conceptual document in China (Neznamov & Naumov, 2017).

The first attempt to elaborate norms on nanotechnology in Russia can be considered the Decree of the Government of the Russian Federation of April 23, 2010 no. 282 "On the national nanotechnology network"[24]. The document, in particular, contains definitions of the concepts "nanoindustry", "nanosystem", "nanotechnology", "nanoindustry products", and "national nanotechnology network".

In terms of developing conceptual approaches, the Model convention on robotics and artificial intelligence of 2017[25] became an interesting experiment. The framework document defines the basic terms, safety standards and ethics in the field of robotics, as well as general issues of accounting and turnover of devices. Among other things, the authors raise the question of the legal personality of robots: it is indicated that in civil circulation a robot can act as a subject of law and be the owner of another robot.

Regarding the regulation of robot devices used in medicine, Federal Law no. 323-FZ of November 21, 2011 "On the principles of protecting the health of citizens in the Russian Federation"[26] is important, which, in particular, defines in Part 3 of Article 34 the content of the concept of high-tech medical care, including "cellular technologies" and the use of "robotic devices". The sectoral by-laws completely duplicate the text of the said norm of the federal law[27, 28].

The list of specific medical devices presented in the Nomenclature classification of medical devices by type, approved by the Order of the Ministry of Healthcare of the Russian Federation dated June 6, 2012 no. 4n "On approval of the nomenclature classification of medical devices"[29], in particular, indicates in paragraph 6 "medical devices for manipulation/restoration of human tissues/organs"[30], a variety of which, according to paragraph 6.3, are "materials for tissue reconstruction"[31]. Some types of medical nanorobots can be attributed

24 Decree of the Government of the Russian Federation no. 282 of 23.04.2010. (2010). *Collection of legislation of the Russian Federation*, *18*, Article 2250.

25 *Model convention on robotics and artificial intelligence*. https://robopravo.ru/uploads/s/z/6/g/z6gj0wkwhv1o/file/6dbrNqgu.pdf

26 On the principles of protecting the health of citizens in the Russian Federation. No. 323-FZ of 21.11.2011. *Collection of legislation of the Russian Federation*, *48*, Article 6724.

27 Order of the Ministry of Healthcare of the Russian Federation no. 824n of 02.10.2019. (2019, November 25). https://normativ.kontur.ru/document?moduleId=1&documentId=348761

28 Order of the Ministry of Healthcare of the Russian Federation no. 796n of 02.12.2014 (2015, February 4) https://base.garant.ru/70859232/

29 Order of the Ministry of Healthcare of the Russian Federation no. 4n of June 6, 2012. (2012). *Rossiyskaya gazeta*, 245.

30 *Ibid*.

31 *Ibid*.

to these items, but for devices that deliver toxic drugs or perform surgical tasks, such a wording seems insufficiently accurate and complete.

Among the draft legal acts, we can mention the draft of federal law "On the turnover of robots, their components (modules)" (Begishev, 2021). The document presents, in particular, the conceptual framework, including the notions of "robot", "robotics", defines various types of devices, such as "service robot" and "civilian robot", formulates the classification of robots and the requirements for the safety of devices, including information safety. The draft also reflects aspects of regulating the turnover of military and other special purpose robots.

The issues of regulation of the use of medical nanorobots represent a complex area of legal regulation, which is not sufficiently implemented at the international or national level. In this case, it seems important to prepare a scientific and methodological basis for future legislative initiatives in the field of nanorobotics regulation.

5. Concept of medical nanorobotics law: doctrinal comprehension

The Russian and foreign legal doctrines do not have a sufficient number of academic articles and monographs related to the intepretation of the role of nanorobotics, especially medical one. At the same time, there are many works devoted to the fundamentals of regulation of robotics and artificial intelligence, which can be extrapolated to the area under study. We propose to classify the whole range of approaches as follows:

1. Scientific works in the field of branch regulation, devoted to the application of technological solutions and focused on civil-legal and criminal-legal aspects, including the issues of responsibility, applied terminology and regulation of the use of devices (Begishev & Khisamova, 2018; Kibalnik & Volosyuk, 2018; Morkhat, 2018a; Vale et al., 2022).

2. Scientific articles concerning conceptual approaches in such areas as the legal status of autonomous devices, problems of their hypothetical legal personality, forecasting and foresight; these materials contain provisions on the proposed documents, fundamental studies of the legal nature of technologies, theoretical approaches to understanding definitions (Pashentsev, 2019; Khisamova & Begishev, 2019; Malko, 2019; Ponkin & Redkina, 2019; Morkhat, 2018b; Gellers, 2021; Mulgan, 2019).

5.1. RoboLaw: foreign and Russian experience

An example of foreign research is an article by a Japanese jurist, which is particularly popular among scholars. The paper examines the norms of legislation and aspects of Japan's state policy on robots. The reason for the developments in this area is the need to compensate for the decrease in the number of workers due to an increase in the average age of the population. The study provides an overview of legal acts containing current norms: Law on road traffic, Law on radio, Law on construction standards, Law on foreign currency and foreign trade. The issues of the legal status of robots, standardization, and legal liability arising from the use of robot devices are also considered. Nurse robots and assistant robots for nursing care of the sick or elderly are noted as medical devices that are important for Japanese society and the economy. Regarding this topic, the paper reflects the issues of regulation of macroscopic medical devices without taking into account the problems of nanorobotics (Nambu, 2016).

In Japan, as well as all over the world, the methodology of the so-called RoboLaw is widespread, i.e. legal and ethical regulation in the field of robotics. The Japanese adaptation of the concept to the issues of medical nanorobots includes measures of civil, administrative and criminal impact; in particular, it is proposed to develop a legal mechanism combining the tools of soft and hard law. As a regulatory framework, it is proposed to create a single Fundamental law on nanotechnology and robotics, and in terms of civil society tools, it is proposed to form a code of so-called nanoethics, or roboethics (Katsunori, 2012).

The European model of robolaw explores the need to create a "special case" for robotic devices due to their ability to act independently (Palmerini et al., 2016). In foreign scientific literature, it is noted that a significant degree of autonomy in software and devices allows considering it as the signs of a legal entity (Mulgan, 2019; Frana & Klein, 2021).

In the legal discussion of the CIS countries, concerns remain regarding the endowment of autonomous devices with the qualities of a legal personality. In the scientific literature it is noted that autonomous software and devices, despite their innovative nature, should not be "humanized", since technologies do not have individuality, soul, consciousness, feelings, morally and materially significant interests (Ponkin & Redkina, 2018). In the focus of medical nanorobotics, the issue of autonomy is seen differently, in particular, in the context of the above-mentioned model based on the laws of robots functioning by Isaac Asimov. The criterion of subordination of a robot to a human and its performance of its function in full accordance with the program or under control can be considered the most important in this area. In this context, the issue of security measures and restrictions related to the circulation and use of medical nanorobots seems to be significant. For example, a ban or restrictions for so-called replicators (robots capable of creating their own copies), since in the course of such activities, unforeseen and adverse consequences for the health or life of a patient may occur.

The criticism of robolaw is based on the provision of reducing the role of law and academic legal science in the context of digital transformation. Proponents of this viewpoint emphasize that coded law will displace lawyers and substitute them with technical specialists. Due to the trends towards technological singularity[32], automated law will take the place of traditional norms and judicial decisions (Astromskis, 2018).

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32 Technological singularity is a hypothetical moment in the future when scientific and technological progress will lead to radical changes in the functioning of human civilization.

5.2. Three fundamental legal problems of the future development of regulation documents

The topical tools for the development of legislation today are the methods of legal modeling, legal forecasting and predictive lawmaking. In order to implement the principles of modern legal methodology, we propose to consider the theoretical and legal contradictions that may negatively affect the development of regulatory framework in the field of medical nanorobotics.

5.2.1. Problem of defining the legal nature of nanorobots

The issues of the legal status of innovative technological developments are rooted in the discussion about the hypothetical legal personality of macrorobots and artificial intelligence (Gulyaeva, 2022). The following contradictions are noted in terms of the problems of medical nanodevices:

– the problem of the legal status of a medical nanorobot, taking into account the degree of autonomy and self-learning of the device;

– the heterogeneity of legal statuses of devices with various technical and functional characteristics;

– the issues of differentiation of the content of the notion of a nanorobot as a physical device or as a complex item including software;

– the doctrinal difficulties related to the classification of medical nanodevices as an object or subject of law;

– the applicability of the category of quasi-legal entity to a nanorobot, as well as the solution of the question of a hypothetical legal personality of the device.

5.2.2. Terminological problem

Another significant theoretical and legal contradiction refers to the problems identified within the study of the unification of the conceptual frameworks of information law (Bachilo, 2015, 2017). In the context of this article, the following issues are discussed:

– the lack of a structured conceptual and categorical framework and understanding of the difference between related concepts and categories of different levels, for example, “biomedical robot”, “nanorobotic system”, “medical nanorobot”;

– the duality associated with the legal identification of the essence of a nanorobot and its software;

– a large number of technological terms that are not related to the terminology of jurisprudence and related humanities.

5.2.3. Tort problem

The issue of the distribution of responsibility for the adverse consequences of a medical nanorobot activity reveals the following theoretical and legal aspects:

– differentiation of responsibility for the consequences of the activity of the device itself and its software;

– differentiation of responsibility for the consequences of the use of nanorobots between medical personnel, technical specialists, and developers.

Conclusions

Medical nanorobots as a research object are a complex phenomenon, including various technological, ethical, and legal aspects. The interdisciplinary nature of social relations formed by the latest biomedical technologies extends far beyond the related humanities and legal sciences. It is assumed that the transformation of legal practice in the future will require lawyers to have special competencies in the field of biomedicine. The issues of robot-human communication are presented in a new way when nanodevices are used literally inside the human body (cells) without direct control by medical professionals, but only under indirect control of the device or a pre-installed software.

1. Model of conceptual and categorical framework

In order to improve legal technology and law-making practice, it is recommended to use modern legal tools, in particular, juridical crowdsourcing. Most drafts of regulatory-legal acts contain a list of terms used in a particular document; at that, definitions are often duplicated, contradict each other and the general logic. It seems useful to form a list of definitions within the framework of each legislative or law-making initiative and publish it in a single open document updated on a regular basis.

In order to prepare a draft Thesaurus in the field of medical nanorobotics (further – the Thesaurus), the following organizational and legal measures are proposed:

– to identify the subjects (further – the Thesaurus operator) who send the terms for publication (further – the project) and the procedure for registering the Thesaurus operator's personal account, including a link to the project and its status: accepted/rejected/under processing;

– to specify the body or structure that deals with the review of projects, generalization and publication of terms (further – the Thesaurus administrator);

– to stipulate the authorities of the Thesaurus administrator in the relevant regulatory legal act containing the rules on the regulation of public relations in the field of medical nanorobotics;

– provided an organization that is not related to public authorities is appointed as the Thesaurus administrator, to appoint a supervising agency or official;

– to prepare requirements for projects to be included in the Thesaurus: a title and details of the regulatory legal act, a list of terms with definitions;

– to form a thematic rubric of the Thesaurus sections and subsections;

– to register the formats of the terms search results: in alphabetical order (for each document) according to the themes of sections and subsections;

– to specify the procedure for making changes to the published Thesaurus terms;

– to consider the possibility of recommending or obliging the subjects of law- and rule-making in the field of medical nanorobotics to bring the terminology of the developed documents in accordance with the Thesaurus;

– it is recommended to form the Thesaurus using the Legal Design software.

In order to unify the conceptual frameworks, it is proposed to analyze the signs of a medical nanorobot and its place among the definitions of this category and to formulate proposals for introducing basic concepts of medical nanorobot law into the Thesaurus, namely: a biomedical robot, a nanorobot system, a medical nanorobot system (a medical nanorobot).

A biomedical robot:

– is a micro, macro or nanoscale device;

– has the functions of movement, relocation, capture and manipulation of an item;

– is able to interact with a patient in vivo or ex vivo, depending on the model and purpose;

– is suitable for therapeutic and surgical manipulations directly under the supervision of medical personnel or autonomously in accordance with the program.

A nanorobototechnical system (a medical nanorobot):

– the size is comparable to the size of a molecule (the smallest samples consist of several dozen atoms);

– is able to move, process and transmit information, execute programs;

– is implemented on the basis of a mechanical device or a living organism;

– includes subgroups of nanorobots and nanomanipulators (nanorobots: molecular devices, nanoengines and DNA nanorobots; nanomanipulators equipped with various technologies, respectively, for example, optical, acoustic, magnetic tweezers or atomic or electron microscopy);

– consists of several modules: technological, mechanical, based on a living organism, software.

A medical nanorobototechnical system (a medical nanorobot):

– refers to nanorobototechnical systems that include groups of nanorobots and nanomanipulators;

– moves, relocates, performs manipulations in a human circulatory system, biofluids, inside tissues and organs;

– the autonomy of functioning is strictly limited by the program;

– interacts with objects on the scale of a molecule, ion; is able to perform manipulations, simulate biosignals, deliver medications to specific cells based on their functional or organic state, perform surgical tasks, diagnostics, detoxification;

– ensures its activity with the energy of blood glucose, light, or heat;

– methodologically refers to a group of microdevices and may include technological, mechanical, software modules, as well as those based on living organisms.

Thus, we propose to add the following terms to the Thesaurus:

– a biomedical robot is a device capable of performing therapeutic, surgical, diagnostic or auxiliary medical tasks both autonomously and as an assistant robot;

– a nanorobototechnical system is a nanoscale device that includes technological, mechanical, software modules and/or modules based on living organisms, and performs manipulations at the scale of a molecule;

– a medical nanorobototechnical system (a medical nanorobot) is a nanoscale device functioning in vivo autonomously enough, capable of receiving energy from the environment (blood glucose, light, heat, ultrasound) and performing the functions of movement, processing and transmitting information, executing programs for the purpose of conducting medical research or therapeutic procedures, including studying biological samples at nanoscale, probing small molecules (including proteins), passing through biofluids for spot surgery.

Under the technological development, it is relevant to further research the role and place of medical nanorobots among other robotic devices. On the one hand, macrorobots, as the most mass technology, form a regulatory framework partially applicable to nanorobots; on the other hand, the conditions of such systems communication with a person in ex vivo format differ from those of the devices functioning in vivo. Microrobots are similar to nanorobots from a regulatory and methodological point of view, but actually have a different range of applications.

In the context of the synergetic development of biomedical technologies and related innovations, it is proposed to supplement the concept of robolaw and roboethics with the concepts of nanorobolaw and nanoroboethics in order to formulate the value content of medical nanorobototechnical law and unite researcgers around a common idea.

2. Risks and safety

Given the scale and speed of technological development, it seems significant to specify common approaches to classification of risks in the field under study:

– communicative and ethical risks (issues of communication between a robot and a human in vivo, as well as interaction between a patient and medical personnel);

– risks in the field of information and technological security (related to unauthorized access to software or otherwise affecting the device functioning);

– communication and methodological risks of a non-legal nature (measurement and interpretation of results in comparison with conservative methods, as well as the degree of influence of device and software developers, technical support);

– legal risks (problems of the legal status of medical devices, issues of delineation of responsibility for adverse consequences).

The most important safety characteristics of a medical nanorobot include biocompatibility and specific autonomy. Biocompatibility means not only safety for a human, but also for the robot itself, at least until the medical procedure is completed. The device autonomy differs from the generally accepted understanding of this quality in robotics. A medical nanorobot should be able to provide its own energy autonomy, the ability to pass through various environments and barriers in a body, as well as to avoid immune provocation. At the same time, the device is completely subordinate to the medical personnel in order to remain safe for the patient.

In the context of the priority of human life and health, the issue of organizational-legal control over the possible replication[33] of nanorobototechnical systems inside a patient's body is relevant.

3. Improving legislation

In terms of approaches to the methodology of developing measures of legal regulation of public relations in the field of medical nanorobotics, several principles are assumed:

– conceptual and proactive nature of law-making activities;

– taking into account the trends of digitalization of law-making and norm-making in the development of approaches (Pashentsev et al., 2019);

– theoretical-legal substantiation of draft regulations;

– preparation of forecast models and legal monitoring at each stage of preparation and implementation of legal norms;

– application of modern juridical technologies in law-making and rule-making (legal experiment, juridical forecasting, regulatory sandboxes, juridical crowdsourcing) (Zaloilo & Pashentsev, 2020);

– interbranch and interdisciplinary nature of public relations related to the use of medical nanorobots suggests that the methodology of law-making activities in this area will require the use of supra-branch tools.

It is assumed that when developing legal norms, it is useful to develop a system of registering norms in the Russian legislation in accordance with the hierarchy of normative-legal acts:

– in federal legislation, to formulate the basic principles of regulation (conceptual framework, classification of devices, security measures, demarcation of authorities of state bodies);

– in the legislation of the subjects, to reflect the norms designed to ensure integration with local legal practice and taking into account local peculiarities, including religious, national, and ethical ones;

– in the by-laws of federal and regional agencies, to formulate variable characteristics (for example, criteria for issuing licenses for certain types of activities related to the use of medical nanorobots);

– to form professional and ethical standards (in cooperation with professional communities and civil society institutions);

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[33] Replication (in virology) is the process of self–reproduction of nucleic acids, genes, and chromosomes.

– in the context of the regulation of nanorobotics and especially its medical application, it is recommended to form a thesaurus of technological terms, registering it in a departmental regulatory act.

In the field of applied research results, a number of legal innovations and methodological recommendations are proposed. In particular, it is recommended to amend Article 34, paragraph 3 of Federal Law no. 323-FZ of November 21, 2011 "On the principles of protecting the health of citizens in the Russian Federation", namely, to supplement the list of types of high-tech medical care with the wording "including medical nanorobototechnical systems" after the words "robotic devices". Article 2 of the "Procedure for organizing the provision of high-tech medical care using the unified state information system in the field of healthcare" approved by Order of the Ministry of Healthcare of the Russian Federation no. 824n of October 2, 2019 "On approval of the procedure for providing high-tech medical care using the unified state information system of healthcare", as well as Article 3 of the "Regulations on the organization of specialized, including high-tech, medical care" approved by the Order of the Ministry of Healthcare of the Russian Federation of December 2, 2014 no. 796n "On approval of the regulations on the organization of the provision of specialized, including high-tech, medical care", which were considered in this work, contain identical norms that completely repeat the text of the above-mentioned law. For this reason, it is also proposed to make additions to these acts concerning nanorobototechnical systems.

In order to improve by-laws, it is proposed to supplement Appendix no. 1, namely, "Nomenclature classification of medical devices by type" approved by Order of the Ministry of Healthcare of the Russian Federation no. 4n of June 6, 2012 "On approval of the nomenclature classification of medical devices", with paragraph 6.1 "Medical nanorobototechnical systems". The concept of nanorobototechnical systems discussed above (outside the context of medical use) can become part of the conceptual and categorical framework and the nomenclature lists related to nanotechnology.

It is assumed that further measures to prepare applied mechanisms of legal regulation will include the development of standards for the provision of high-tech medical care in the form of the use of nanorobototechnical systems. It is recommended to formulate these rules based on a system of standards adopted in other fields of medicine and registered in the Orders of the Ministry of Healthcare[34].

We propose to register at the level of federal law norms the obligation to use biocompatible materials for manufacturing of medical nanorobots and the restriction of devices replication.

The sphere of nanorobotics refers to the newest, sixth technological paradigm, changing the legal reality. The issues of communication between nanorobots and humans in the in vivo format are becoming a fundamentally new area of public relations, which form a request for a new type of standards. Ethical rules and standards of professional activity

[34] See, for example: Order of the Ministry of Healthcare of the Russian Federation no. 1468n of 24.12.2012. (2013, 10 June). *Rossiyskaya gazeta, special issue, 123/1*.

come to the fore, being not less important than the civil-legal and criminal-legal aspects. In the legal doctrine, under the influence of large-scale technological modernization, basic concepts are being transformed. Interdisciplinary methodology irreversibly changes the classical academic research tools. The educational process in jurisprudence reveals the prospects for development in the context of the need to train lawyers capable of legal practice in the field of innovative biomedicine.

References

Aramesh, M., Forró, C., Dorwling-Carter, L., Lüchtefeld, I., Schlotter, T., Ihle, S. J., Shorubalko, I., Hosseini, V., Momotenko, D., Zambelli, T., Klotzsch, E., & Vörös, J. (2019). Localized detection of ions and biomolecules with a force-controlled scanning nanopore microscope. *Nature nanotechnology*, *14*(8), 791–798. https://doi.org/10.1038/s41565-019-0493-z

Aseeva, I. A. (2017). Axiological priorities of the VI technological mode *Epistemology & Philosophy of Science*, *51*(1), 124–137. (In Russ.). https://doi.org/10.5840/eps201751114

Asimov, I. (1942). Runaround. In *Astounding Science Fiction*. New York.

Astromskis, P. (2018). In Critique of RoboLaw: The Model of SmartLaw. In V. Müller (Ed.). *Philosophy and Theory of Artificial Intelligence 2017. PT-AI 2017*. *SeriesStudies in Applied Philosophy, Epistemology and Rational Ethics*, *44*. Springer, Cham.

Bachilo, I. L. (2015). *Conceptual framework of informational law*: collection of research works (pp. 8–17). Moscow: Kanon-Plyus. (In Russ.).

Bachilo, I. L. (2017). *Conceptual framework of informational law*: collection of research works (pp. 12–28). Moscow: Kanon-Plyus. (In Russ.).

Bartkowski, P., Gawinski, F., & Pawliszak, L. (2022). E-Morph as a New Adaptive Actuator for Soft Robotics. *IEEE Robotics and Automation Letter*, *7*(4), 8831–8836. https://doi.org/10.1109/LRA.2022.3189169

Begishev, I. R. (2021). Draft of a Federal Law "On circulation of robots and their components (modules)". *Actual Problems of Economics and Law, 15*(2), 379–391. (In Russ.). https://doi.org/10.21202/1993-047X.15.2021.2.379-391

Begishev, I. R., Khisamova, Z. I. (2018). Criminological Risks of Using Artificial Intelligence. *Vserossiiskii kriminologicheskii zhurnal = Russian Journal of Criminology*, *12*(6), 767–775. (In Russ.). https://doi.org/10.17150/2500-4255.2018.12(6).767-775

Chen, S., Wang, Y., Nie, T., Bao, C., Wang, C., Xu, T., Lin, Q., Qu, D. H., Gong, X., Yang, Y., Zhu, L., & Tian, H. (2018). An Artificial Molecular Shuttle Operates in Lipid Bilayers for Ion Transport. *Journal of the American Chemical Society*, *140*(51), 17992–17998. https://doi.org/10.1021/jacs.8b09580

Deng, X. et al. (2023). Magnetic Micro/nanorobots for biological detection and targeted delivery. *Biosensors and Bioelectronics*, *222*, 114960. https://doi.org/10.1016/j.bios.2022.114960

Diller, E., & Sitti, M. (2013). Micro-Scale Mobile Robotics. *Foundations and Trends® in Robotics*, *2*(3), 143–259. http://dx.doi.org/10.1561/2300000023

Erbas-Cakmak, S., Leigh, D. A., McTernan, C. T., & Nussbaumer, A. L. (2015). Artificial Molecular Machines. *Chemical Reviews*, *115*(18), 10081–10206. https://doi.org/10.1021/acs.chemrev.5b00146

Fortunato, Gabriele Maria, Batoni, Elisa, Bonatti, Amedeo Franco, Giovanni, Vozzi, & Carmelo, De Maria. (2022). Surface reconstruction and tissue recognition for robotic-based in situ bioprinting. *Bioprinting*, *26*, e00195. https://doi.org/10.1016/j.bprint.2022.e00195

Frana, P. L., & Klein, M. J. (2021). *Encyclopedia of Artificial Intelligence: The Past, Present, and Future of AI*. Santa-Barbara, California. ABC-Clio.

Fukuda, Toshio, Nakajima, Masahiro, & Kojima, Masaru. (2010). Micro-Nano Robotics and Automation System. *IFAC Proceedings Volumes*, *43*(8), 20–25. https://doi.org/10.3182/20100712-3-FR-2020.00005

Gardini, L., Heissler, S. M., Arbore, C., Yang, Y., Sellers, J. R., Pavone, F. S., & Capitanio, M. (2018). Dissecting myosin-5B mechanosensitivity and calcium regulation at the single molecule level. *Nature communications*, *9*(1), 2844. https://doi.org/10.1038/s41467-018-05251-z

Gellers, Joshua C. (2021). *Rights for Robots Artificial Intelligence, Animal and Environmental Law*. NY: Routledge.

Guillaume-Gentil, O., Potthoff, E., Ossola, D., Franz, C. M., Zambelli, T., & Vorholt, J. A. (2014). Force-controlled manipulation of single cells: from AFM to FluidFM. *Trends in biotechnology*, *32*(7), 381–388. https://doi.org/10.1016/j.tibtech.2014.04.008

Guix, M., Mayorga-Martinez, C. C., & Merkoçi, A. (2014). Nano/micromotors in (bio)chemical science applications. *Chemical reviews*, *114*(12), 6285–6322. https://doi.org/10.1021/cr400273r

Gulyaeva, P. S. (2022). Quasi-legal personality of artificial intelligence: theoretical and legal aspects. *Bulletin of the Moscow City Pedagogical University. "Pedagogy and Psychology" Series, 2*(46), 58–69. (In Russ.). https://doi.org/10.25688/2076-9113.2022.46.2.06

Jamali, Hamid R., Azadi-Ahmadabadi, Ghasem, & Asadi, Saeid. (2018). Interdisciplinary relations of converging technologies: Nano-Bio-Info-Cogno (NBIC). *Scientometrics*, *116*(11), 1055–1073.

Ji, Y., Lin, X., Wu, Z., Wu, Y., Gao, W., & He, Q. (2019). Macroscale Chemotaxis from a Swarm of Bacteria-Mimicking Nanoswimmers. *Angewandte Chemie International edition*, *58*(35), 12200–12205. https://doi.org/10.1002/anie.201907733

Jingui, Qian, Jifeng, Ren, Yi, Liu, Raymond H. W., Lam, & Joshua E.-Y., Lee. (2020). Reusable acoustic tweezers enable 2D patterning of microparticles in microchamber on a disposable silicon chip superstrate. *IEEE SENSORS* (pp. 1–4). https://doi.org/10.1109/sensors47125.2020.9278717

Katsunori, K. (2012). Nanotechnology and Medical Robotics; Legal and Ethical Responsibility. *Waseda Bulletin of Comparative Law*, *30*, 1–6.

Khabriyeva, T., Chernogor, N. (2020). *The future of law: the legacy of academician V. S. Stepin and legal science*. Moscow: Rossiiskaya akademiya nauk; Institut zakonodatel'stva i sravnitel'nogo pravovedeniya pri Pravitel'stve Rossiiskoi Federatsii; INFRA-M. (In Russ.). https://doi.org/10.12737/1112960

Khisamova, Z. I., & Begishev, I. R. (2019). On Methods to Legal Regulation of Artificial Intelligence in the World. *International Journal of Innovative Technology and Exploring Engineering*, *9*(1), 515–520. https://doi.org/10.35940/ijitee.A9220.119119

Kibalnik, A. G., Volosyuk, P. V. (2018). Artificial intelligence: doctrinal criminal law questions awaiting answers. *Legal Science and Practice: Journal of Nizhny Novgorod Academy of the Ministry of Internal Affairs of Russia*, *4*(44), 173–178. (In Russ.). https://doi.org/10.24411/2078-5356-2018-10428

Kuijpers, Louis, van Laar, Theo, Janissen, Richard, & Dekker, Nynke H. (2022). Characterizing single-molecule dynamics of viral RNA-dependent RNA polymerases with multiplexed magnetic tweezers. *STAR Protocols, 3*(3), 101606, 1–19. https://doi.org/10.1016/j.xpro.2022.101606

Li, J., Esteban-Fernández de Ávila, B., Gao, W., Zhang, L., & Wang, J. (2017). Micro/Nanorobots for Biomedicine: Delivery, Surgery, Sensing, and Detoxification. *Science Robotics*, *2*(4), eaam6431. https://doi.org/10.1126/scirobotics.aam6431

Li, M., Xi, N., Wang, Y. et al. (2019). Advances in atomic force microscopy for single-cell analysis. *Nano Research*, *12*, 703–718. https://doi.org/10.1007/s12274-018-2260-0

Li, M., Xi, N., Wang, Y., & Liu, L. (2021). Progress in Nanorobotics for Advancing Biomedicine. *IEEE transactions on bio-medical engineering*, *68*(1), 130–147. https://doi.org/10.1109/TBME.2020.2990380

Li, T., Mao, C., Shen, J., & Zhou, M. (2022). Three laws of design for biomedical micro/nanorobots. *Nano Today*, *45*, 101560, https://doi.org/10.1016/j.nantod.2022.101560

Li, X., Liu, C., Chen, S., Wang, Y., Cheng, S. H., & Sun, D. (2017). In Vivo Manipulation of Single Biological Cells With an Optical Tweezers-Based Manipulator and a Disturbance Compensation Controller, *IEEE Transactions on Robotics*, *33*(5), 1200–1212. https://doi.org/10.1109/TRO.2017.2718554

Malko, A. V. (2019). The draft concept of the Russian legal policy in the field of artificial intelligence as a doctrinal document. *Baltic Humanitarian Journal*, *8*(29), 348–352. (In Russ.). https://doi.org/10.26140/bgz3-2019-0804-0081

Marks, J. L. A., & Cyr, S. K. (2018). Government Regulation of Nanorobots in Medicine: How the FDA and PTO Handle These New Technologies. *The Journal of Robotics, Artificial Intelligence & Law*, *1*(4), 217–230.

Min, Sun, Weisi, Lia, Cheng, Zhang, Shuangxi, Lia, Fayong, Zhou, Yuntao, Zhu, & Xiaoyang, Zhou. (2022). Da Vinci Xi™ robot-assisted liver resection. *Intelligent Surgery*, *1*, 16–20. https://doi.org/10.1016/j.isurg.2021.10.001

Morkhat, P. M. (2018a). Artificial intelligence unit as electronic personality. *Bulletin MSRU. Series: Jurisprudence*, *2*, 61–73. (In Russ.). https://doi.org/10.18384/2310-6794-2018-2-61-73

Morkhat, P. M. (2018b). *Legal personality of a unit of artificial intelligence. Civi-legal research*. Moscow: Yuniti-Dana. (In Russ.).

Mulgan, T. (2019). Corporate Agency and Possible Futures. *Journal of Business Ethics*, *154*(4), 901–916. https://doi.org/10.1007/s10551-018-3887-1

Muscariello, L., Rosso, F., Marino, G., Giordano, A., Barbarisi, M., Cafiero, G., & Barbarisi, A. (2005). A critical overview of ESEM applications in the biological field. *Journal of cellular physiology*, *205*(3), 328–334. https://doi.org/10.1002/jcp.20444

Naidoo, S. (2021). *Biocompatibility Testing of Medical Devices*. Burlington: Arcler Press.

Nambu, T. (2016). Legal regulations and public policies for next-generation robots in Japan. *AI & SOCIETY*, *31*, 483–500. https://doi.org/10.1007/s00146-015-0628-1
Neuman, Keir C., Nagy, Attila. (2008). Single-molecule force spectroscopy: optical tweezers, magnetic tweezers and atomic force microscopy. *Nature Methods*, *5*(6), 491–506.
Neznamov, A., Naumov, V. (2017). On the regulation of robotics in Russia and in the world. *Legal Studies*, *8*, 14–25. (In Russ.). https://doi.org/10.25136/2409-7136.2017.8.23292
Norasi, Hamid, Tetteh, Emmanuel, Law, Katherine E., Sid, Ponnal, Hallbeck, Susan, & Tollefson, Matthew. (2022). Intraoperative workload during robotic radical prostatectomy: Comparison between multi-port da Vinci Xi and single port da Vinci SP robots. *Applied Ergonomics*, *104*, 103826. https://doi.org/10.1016/j.apergo.2022.103826
Palmerini, E., Bertolini, A., Battaglia, F., Koops, B.-J., Carnevale, A., & Salvini, P. (2016). RoboLaw: Towards a European framework for robotics regulation. *Robotics and Autonomous Systems*, *86*, 78–85. https://doi.org/10.1016/j.robot.2016.08.026
Pashentsev, D. A. (2019). Lexical and semantic features of the law-making language in the conditions of digitalization. In D. A. Pashentsev, M. V. Zaloilo (Eds.). *Law-making language within the context of digitalization of social relations. Collection of scientific articles* (pp. 143–148). Moscow: The Institute of Legislation and Comparative Law under the Government of the Russian Federation: INFRA-M. (In Russ.).
Pashentsev, D. A., Zaloilo, M. V., & Dorskaya, A. A. (2021). *Changing of Technological Orders and Legal Development of Russia*. Moscow: IZISP: Norma: INFRA-M. (In Russ.).
Pashentsev, D. A., Zaloilo, M. V., Ivanyuk, O. A., & Golovina, A. A. (2019). *The digitalization of law-making: the search for new solutions*. Moscow: Institut zakonodatel'stva i sravnitel'nogo pravovedeniya pri Pravitel'stve Rossiiskoi Federatsii: INFRA-M. (In Russ.).
Ponkin, I. V., & Redkina, A. I. (2018). Artificial Intelligence from the Point of View of Law. *RUDN Journal of Law, 22*(1), 91–109. (In Russ.). https://doi.org/10.22363/2313-2337-2018-22-1-91-109
Ponkin, I., & Redkina, A. (2019). Digital formalization of law. *International Journal of Open Information Technologies*, *7*(1), 39–48. (In Russ.).
Qi, Hu, Teng, Ma, Qi, Zhang, Jimin, Wang, Ye, Yang, Feiyan, Cai, & Hairong, Zheng. (2021). 3-D Acoustic Tweezers Using a 2-D Matrix Array With Time-Multiplexed Traps. IEEE *Transactions on Ultrasonics, Ferroelectronics, and Frequency Control*, *68*(12), 3646–3653. https://doi.org/10.1109/TUFFC.2021.3098191
Qing, Wang, Shuhan, Chen, Jia, Zhou, & Antoine, Riaud. (2022). *Laser-guided acoustic tweezers*. National Natural Science Foundation of China, State Key Lab of ASIC and System, Fudan University (pp. 1–18). https://arxiv.org/abs/2203.14497
Rong, Liu, Guo-Dong, Zhao, Wen-Bo, Zou, Xiu-Ping, Zhang, Shuai, Xu, Yang, Wang, Yan-Zhe, Liu, Yuan-Xing, Gao, Zhi-Peng, & Zhoua, Yu-Yao Song. (2022). Single-port robot-assisted hepatic left lateral sectionectomy using the da Vinci SP® system: A case report. *Intelligent Surgery*, *2*, 6–9. https://doi.org/10.1016/j.isurg.2022.02.002
Rothemund, P. W. (2006). Folding DNA to create nanoscale shapes and patterns. *Nature*, *440*(7082), 297–302. https://doi.org/10.1038/nature04586
Shi, C., Luu, D. K., Yang, Q., Liu, J., Chen, J., Ru, C., Xie, S., Luo, J., Ge, J., & Sun, Y. (2016). Recent advances in nanorobotic manipulation inside scanning electron microscopes. *Microsystems & Nanoengineering*, *2*, 16024. https://doi.org/10.1038/micronano.2016.24
Suulker, C., Skach, S., & Althoefer, K. (2022). Soft Robotic Fabric Actuator With Elastic Bands for High Force and Bending Performance in Hand Exoskeletons. *IEEE Robotics and Automation Letter*, *7*(4), 10621–10627. https://doi.org/10.1109/LRA.2022.3194883
Sweeney, Aldrin. (2020). Incorporating NBIC social/ethical issues into STEM teacher education programmes. *Canada-Caribbean Institute Journal*, *1*(1): Proceedings of the Canada-Caribbean Research Symposium. Canada-Caribbean Institute. Brock University Open Journal System. 2020. https://journals.library.brocku.ca/index.php/cancarib/article/view/2369#
Taherkhani, S., Mohammadi, M., Daoud, J., Martel, S., & Tabrizian, M. (2014). Covalent binding of nanoliposomes to the surface of magnetotactic bacteria for the synthesis of self-propelled therapeutic agents. *ACS Nano*, *8*(5), 5049–5060. https://doi.org/10.1021/nn5011304
Vale, Daniel, El-Sharif, Ali, & Muhammed, Ali. (2022). Explainable artifcial intelligence (XAI) post-hoc explainability methods: risks and limitations in non-discrimination law. *AI and Ethics*, *2*, 815–826. https://doi.org/10.1007/s43681-022-00142-y
Villa, K., & Pumera, M. (2019). Fuel-free light-driven micro/nanomachines: artificial active matter mimicking nature. *Chemical Society Reviews*, *48*(19), 4966–4978. https://doi.org/10.1039/C9CS00090A

Wan, M., Liu, Z., Li, T., Chen, H., Wang, Q., Chen, T., Tao, Y., & Mao, C. (2021). Zwitterion-Based Hydrogen Sulfide Nanomotors Induce Multiple Acidosis in Tumor Cells by Destroying Tumor Metabolic Symbiosis. *Angewandte Chemie International Edition*, *60*(29), 16139–16148. https://doi.org/10.1002/anie.202104304

Wang, H., & Pumera, M. (2015). Fabrication of Micro/Nanoscale Motors. *Chemical Reviews*, *115*(16), 8704–8735. https://doi.org/10.1021/acs.chemrev.5b00047

Wang, Joseph, & Wei, Gao. (2012). Nano/Microscale Motors: Biomedical Opportunities and Challenges. *ACS Nano*, *6*(7), 5745–5751.

Wenyan, Qiao, Linglin, Zhou, Zhihao, Zhao, Di, Liua, Shaoxin, Lia, Jie, Ana, Xinyuan, Lia, Yikui, Gao, Peiyuan, Yang, Jiaqi Liu, Zhong, Lin, Wang, & Jie, Wang. (2022). A self-powered vector motion sensor for smart robotics and personalized medical rehabilitation. *Nano Energy*, *104*, 1–10. https://doi.org/10.1016/j.nanoen.2022.107936

Xu, X., Saw, P. E., Tao, W., Li, Y., Ji, X., Bhasin, S., Liu, Y., Ayyash, D., Rasmussen, J., Huo, M., Shi, J., & Farokhzad, O. C. (2017). ROS-Responsive Polyprodrug Nanoparticles for Triggered Drug Delivery and Effective Cancer Therapy. *Advanced materials (Deerfield Beach, Fla.)*, *29*(33), https://doi.org/10.1002/adma.201700141

Xue, S. (2022). The Application of Virtual Metacognitive Network Model in Preschool Guiding Art Network Teaching, *6th International Conference on Intelligent Computing and Control Systems (ICICCS)* (pp. 672–675). https://doi.org/10.1109/ICICCS53718.2022.9788219

You, M., Chen, C., Xu, L., Mou, F., & Guan, J. (2018). Intelligent Micro/nanomotors with Taxis. *Accounts of Chemical Research*, *51*(12), 3006–3014. https://doi.org/10.1021/acs.accounts.8b00291

Yuan, K., Aftoni, A., & Çobanoğlu, Ö. (2020). The Effect of Problem-Based Learning Model and Blended Learning Model to Metacognitive Awareness as a Reflection Towards a New Normal Era. *Jurnal Pendidikan Teknologi dan Kejuruan*, *26*(2), 183–188. https://doi.org/10.21831/jptk.v26i2.32783

Zaloilo, M. V., & Pashentsev, D. A. (Ed.). (2020). *Modern legal technologies in law-making*. Moscow: IZISP: Norma: INFRA-M. (In Russ.).

Zholobova, Yu. V., & Schastlivceva, E. A. (2020). NBICS-technologies and the problem of anthropological evolution. *Herald of Vyatka State University*, *3*(137), 7–19. (In Russ.).

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RSCI Author ID: https://www.elibrary.ru/author_items.asp?authorid=1002457

Conflict of interest

The author declares no conflict of interest.

Financial disclosure

The research had no sponsorship.

Article history

Date of receipt – September 8, 2022
Date of approval – January 17, 2022
Date of acceptance – March 6, 2023
Date of online placement – March 10, 2023

Научная статья
УДК 34:620.3:004
EDN: https://elibrary.ru/wnraoe
DOI: https://doi.org/10.21202/jdtl.2023.4

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Медицинские нанороботы в фокусе права

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Ключевые слова

Айзек Азимов,
здравоохранение,
медицина,
медицинский робот,
наноробот,
право,
регулирование,
робототехника,
цифровые технологии,
этика,
in vivo

Аннотация

Цели: формирование доктринальных основ и механики правового регулирования применения медицинских нанороботов, концептуализация идеи наноробототехнического права в границах его базовых дефиниций, норм безопасности, рисков, типологии устройств, юридических параметров технологических терминов.

Методы: познавательный инструментарий представлен в виде интеграции общенаучных и современных специальных юридических методов (в том числе методов сравнительного правоведения, правового моделирования и юридического прогнозирования, NBICS-конвергенции), в совокупности позволяющих выделить в объекте изучения не только собственно правовые, но и антропологические, биомедицинские, информационные, механистические исследовательские проекции.

Результаты: сформулировано авторское определение понятия медицинского наноробота; исследовано правовое содержание и квазиправовые аспекты дефиниции, имеющие значение для теоретического и прикладного развития терминологии; выявлены признаки смежных понятий (биомедицинский робот, наноробототехническая система, медицинская наноробототехническая система), и установлены логические связи между ними; проведена классификация основных видов рисков, связанных с практическим применением медицинских нанороботов; выявлен перечень теоретико-правовых противоречий, которые потенциально способны негативно повлиять на будущее развитие регуляторной практики; рассмотрен отечественный и зарубежный опыт правовой регламентации и доктринального осмысления проблем медицинской наноробототехники (на примере США, Японии, Европы, Китая).

Научная новизна: в условиях междисциплинарного научно-исследовательского вакуума предпринята попытка комплексного рассмотрения понятия медицинского наноробота в технологическом, юридическом и коммуникативном ключе («робот-человек» в наномасштабе) на базе передовых научных изысканий, определяющих основы будущего наноробототехнического права. Синергетическое развитие биомедицинских и смежных технологий, отраженное в моделях робоправа и робоэтики, рекомендовано дополнить относительно самостоятельными концептами нанобобоправа и наноробоэтики.

Практическая значимость: на основе анализа действующей в России и за рубежом системы правового регулирования определены механизмы совершенствования отечественного законодательства, в том числе с учетом достижений правового краудсорсинга. В рамках социогуманитарной проблематики формируется вклад в развитие правовой, социологической, психологической науки. Подготовлена научно-методологическая база для дальнейших юридических исследований и правотворческой деятельности в сфере медицинской наноробототехники.

Для цитирования

Гуляева, П. С. (2023). Медицинские нанороботы в фокусе права. *Journal of Digital Technologies and Law*, *1*(1), 89–122. https://doi.org/10.21202/jdtl.2023.4

Список литературы

Асеева, И. А. (2017). Аксиологические приоритеты VI технологического уклада. *Эпистемология и философия науки*, *51*(1), 124–137. EDN: https://elibrary.ru/yqyrun. DOI: https://doi.org/10.5840/eps201751114

Бачило, И. Л. (2017). *Понятийный аппарат в информационном праве*: сборник научных работ (с. 12–28). Москва: Канон-Плюс.

Бачило, И. Л. (2015). *Понятийный аппарат информационного права*: сборник научных работ (pp. 8–17). Москва: Канон-Плюс.

Бегишев, И. Р., Хисамова, З. И. (2018). Криминологические риски применения искусственного интеллекта. *Всероссийский криминологический журнал*, *12*(6), 767–775. EDN: https://elibrary.ru/yystvz. DOI: https://doi.org/10.17150/2500-4255.2018.12(6).767-775

Бегишев, И. Р. (2021). Проект федерального закона «Об обороте роботов, их составных частей (модулей)». *Актуальные проблемы экономики и права*, *15*(2), 379–391. EDN: https://elibrary.ru/nxzfpk. DOI: https://doi.org/10.21202/1993-047X.15.2021.2.379-391

Гуляева, П. С. (2022). Квазиправосубъектность искусственного интеллекта: теоретико-правовые аспекты. *Вестник Московского государственного педагогического университета*. *Серия: Юридические науки*, *2*(46), 58–69. EDN: https://elibrary.ru/qbdkre. DOI: https://doi.org/10.25688/2076-9113.2022.46.2.06

Жолобова, Ю. В., Счастливцева, Е. А. (2020). НБИКС-технологии и проблема антропологической эволюции. *Вестник Вятского государственного университета*, *3*(137), 7–19.

Залоило, М. В., Пашенцев, Д. А. (ред.). (2020). *Современные юридические технологии в правотворчестве*: научно-практическое пособие. Москва: ИЗиСП: Норма: ИНФРА-М. https://elibrary.ru/vtejsu

Кибальник, А. Г., Волосюк, П. В. (2018). Искусственный интеллект: вопросы уголовно-правовой доктрины, ожидающие ответов. *Юридическая наука и практика: Вестник Нижегородской академии МВД России*, *4*(44), 173–178. EDN: https://elibrary.ru/yszmpj. DOI: https://doi.org/10.24411/2078-5356-2018-10428

Малько, А. В. (2019). Проект концепции российской правовой политики в сфере искусственного интеллекта как доктринальный документ. *Балтийский гуманитарный журнал*, *8*(29), 348–352. EDN: https://elibrary.ru/sjqbob. DOI: https://doi.org/10.26140/bgz3-2019-0804-0081

Морхат, П. М. (2018a). *Правосубъектность юнитов искусственного интеллекта Гражданско-правовое исследование*: монография. Москва: ЮНИТИ-ДАНА.

Морхат, П. М. (2018b). Юнит искусственного интеллекта как электронное лицо. *Вестник Московского государственного областного университета. Серия: Юриспруденция*, *2*, 61–73. https://doi.org/10.18384/2310-6794-2018-2-61-73

Незнамов, А. В., Наумов, В. Б. (2017). Вопросы развития законодательства о робототехнике в России и в мире. *Юридические исследования*, *8*, 14–25. EDN: https://elibrary.ru/zcssfv. DOI: https://doi.org/10.25136/2409-7136.2017.8.23292

Пашенцев, Д. А. (2019). Лексико-семантические особенности языка правотворчества в условиях цифровизации. В сб. Д. А. Пашенцев, М. В. Залоило (ред.). *Язык правотворчества в условиях цифровизации общественных отношений: сборник научных трудов* (с. 143–148). Москва: Институт законодательства и сравнительного правоведения при Правительстве Российской Федерации: ИНФРА-М.

Пашенцев, Д. А., Залоило, М. В., Дорская, А. А. (2021). *Смена технологических укладов и правовое развитие России*. Москва: ИЗиСП: Норма: ИНФРА-М.

Пашенцев, Д. А., Залоило, М. В., Иванюк, О. А., Головина, А. А. (2019). *Цифровизация правотворчества: поиск новых решений: монография*. Москва: Институт законодательства и сравнительного правоведения при Правительстве Российской Федерации: ИНФРА-М, 2019. https://elibrary.ru/qrnijy

Понкин, И. В., Редькина, А. И. (2019). Цифровая формализация права. *International Journal of Open Information Technologies*, 7(1), 39–48.

Понкин, И. В., Редькина, А. И. (2018). Искусственный интеллект с точки зрения права. *Вестник Российского университета дружбы народов. Серия: Юридические науки*, *22*(1), 91–109. EDN: https://elibrary.ru/yvxkva. DOI: https://doi.org/10.22363/2313-2337-2018-22-1-91-109

Хабриева, Т. Я., Черногор, Н. Н. (2020). *Будущее права. Наследие академика В. С. Степина и юридическая наука*. Москва: Российская академия наук; Институт законодательства и сравнительного правоведения при Правительстве Российской Федерации; ИНФРА-М. https://doi.org/10.12737/1112960

Asimov, I. (1942). Runaround. In Astounding Science Fiction. New York.

Aramesh, M., Forró, C., Dorwling-Carter, L., Lüchtefeld, I., Schlotter, T., Ihle, S. J., Shorubalko, I., Hosseini, V., Momotenko, D., Zambelli, T., Klotzsch, E., & Vörös, J. (2019). Localized detection of ions and biomolecules with a force-controlled scanning nanopore microscope. *Nature nanotechnology*, *14*(8), 791–798. https://doi.org/10.1038/s41565-019-0493-z

Astromskis, P. (2018). In Critique of RoboLaw: The Model of SmartLaw. In V. Müller (Ed.). *Philosophy and Theory of Artificial Intelligence 2017. PT-AI 2017. Series Studies in Applied Philosophy, Epistemology and Rational Ethics*, *44*. Springer, Cham.

Bartkowski, P., Gawinski, F., & Pawliszak, L. (2022). E-Morph as a New Adaptive Actuator for Soft Robotics. *IEEE Robotics and Automation Letter*, *7*(4), 8831–8836. https://doi.org/10.1109/LRA.2022.3189169

Chen, S., Wang, Y., Nie, T., Bao, C., Wang, C., Xu, T., Lin, Q., Qu, D. H., Gong, X., Yang, Y., Zhu, L., & Tian, H. (2018). An Artificial Molecular Shuttle Operates in Lipid Bilayers for Ion Transport. *Journal of the American Chemical Society*, *140*(51), 17992–17998. https://doi.org/10.1021/jacs.8b09580

Deng, X. et al. (2023). Magnetic Micro/nanorobots for biological detection and targeted delivery. *Biosensors and Bioelectronics*, *222*, 114960. https://doi.org/10.1016/j.bios.2022.114960

Diller, E., & Sitti, M. (2013). Micro-Scale Mobile Robotics. *Foundations and Trends® in Robotics*, *2*(3), 143–259. http://dx.doi.org/10.1561/2300000023

Erbas-Cakmak, S., Leigh, D. A., McTernan, C. T., & Nussbaumer, A. L. (2015). Artificial Molecular Machines. *Chemical Reviews*, *115*(18), 10081–10206. https://doi.org/10.1021/acs.chemrev.5b00146

Fortunato, Gabriele Maria, Batoni, Elisa, Bonatti, Amedeo Franco, Giovanni, Vozzi, & Carmelo, De Maria. (2022). Surface reconstruction and tissue recognition for robotic-based in situ bioprinting. *Bioprinting*, *26*, e00195. https://doi.org/10.1016/j.bprint.2022.e00195

Frana, P. L., & Klein, M. J. (2021). *Encyclopedia of Artificial Intelligence: The Past, Present, and Future of AI*. Santa-Barbara, California. ABC-Clio.

Fukuda, Toshio, Nakajima, Masahiro, & Kojima, Masaru. (2010). Micro-Nano Robotics and Automation System. *IFAC Proceedings Volumes*, *43*(8), 20–25. https://doi.org/10.3182/20100712-3-FR-2020.00005

Gardini, L., Heissler, S. M., Arbore, C., Yang, Y., Sellers, J. R., Pavone, F. S., & Capitanio, M. (2018). Dissecting myosin-5B mechanosensitivity and calcium regulation at the single molecule level. *Nature communications*, *9*(1), 2844. https://doi.org/10.1038/s41467-018-05251-z

Gellers, Joshua C. (2021). *Rights for Robots Artificial Intelligence, Animal and Environmental Law*. NY: Routledge.

Guillaume-Gentil, O., Potthoff, E., Ossola, D., Franz, C. M., Zambelli, T., & Vorholt, J. A. (2014). Force-controlled manipulation of single cells: from AFM to FluidFM. *Trends in biotechnology*, *32*(7), 381–388. https://doi.org/10.1016/j.tibtech.2014.04.008

Guix, M., Mayorga-Martinez, C. C., & Merkoçi, A. (2014). Nano/micromotors in (bio)chemical science applications. *Chemical reviews*, *114*(12), 6285–6322. https://doi.org/10.1021/cr400273r

Jamali, Hamid R., Azadi-Ahmadabadi, Ghasem, & Asadi, Saeid. (2018). Interdisciplinary relations of converging technologies: Nano-Bio-Info-Cogno (NBIC). *Scientometrics*, *116*(11), 1055–1073.

Ji, Y., Lin, X., Wu, Z., Wu, Y., Gao, W., & He, Q. (2019). Macroscale Chemotaxis from a Swarm of Bacteria-Mimicking Nanoswimmers. *Angewandte Chemie International edition*, *58*(35), 12200–12205. https://doi.org/10.1002/anie.201907733

Jingui, Qian, Jifeng, Ren, Yi, Liu, Raymond, H. W. Lam, & Joshua E.-Y., Lee. (2020). Reusable acoustic tweezers enable 2D patterning of microparticles in microchamber on a disposable silicon chip superstrate. *IEEE SENSORS* (pp. 1–4). https://doi.org/10.1109/sensors47125.2020.9278717

Katsunori, K. (2012). Nanotechnology and Medical Robotics; Legal and Ethical Responsibility. *Waseda Bulletin of Comparative Law*, *30*, 1–6.

Khisamova, Z. I., & Begishev, I. R. (2019). On Methods to Legal Regulation of Artificial Intelligence in the World. *International Journal of Innovative Technology and Exploring Engineering*, *9*(1), 515–520. EDN: https://elibrary.ru/pqjfko. DOI: https://doi.org/10.35940/ijitee.A9220.119119

Kuijpers, Louis, van Laar, Theo, Janissen, Richard, & Dekker, Nynke H. (2022). Characterizing single-molecule dynamics of viral RNA-dependent RNA polymerases with multiplexed magnetic tweezers. *STAR Protocols, 3*(3), 101606, 1–19. https://doi.org/10.1016/j.xpro.2022.101606

Li, J., Esteban-Fernández de Ávila, B., Gao, W., Zhang, L., & Wang, J. (2017). Micro/Nanorobots for Biomedicine: Delivery, Surgery, Sensing, and Detoxification. *Science Robotics*, *2*(4), eaam6431. https://doi.org/10.1126/scirobotics.aam6431

Li, M., Xi, N., Wang, Y. et al. (2019). Advances in atomic force microscopy for single-cell analysis. *Nano Research*, *12*, 703–718. https://doi.org/10.1007/s12274-018-2260-0

Li, M., Xi, N., Wang, Y., & Liu, L. (2021). Progress in Nanorobotics for Advancing Biomedicine. *IEEE transactions on bio-medical engineering*, *68*(1), 130–147. https://doi.org/10.1109/TBME.2020.2990380

Li, T., Mao, C., Shen, J., & Zhou, M. (2022). Three laws of design for biomedical micro/nanorobots. *Nano Today*, *45*, 101560. https://doi.org/10.1016/j.nantod.2022.101560

Li, X., Liu, C., Chen, S., Wang, Y., Cheng, S. H., & Sun, D. (2017). In Vivo Manipulation of Single Biological Cells With an Optical Tweezers-Based Manipulator and a Disturbance Compensation Controller, *IEEE Transactions on Robotics*, *33*(5), 1200–1212. https://doi.org/10.1109/TRO.2017.2718554

Marks, J. L. A., & Cyr, S. K. (2018). Government Regulation of Nanorobots in Medicine: How the FDA and PTO Handle These New Technologies. *The Journal of Robotics, Artificial Intelligence & Law*, *1*(4), 217–230

Min, Sun, Weisi, Lia, Cheng, Zhang, Shuangxi, Lia, Fayong, Zhou, Yuntao, Zhu, & Xiaoyang, Zhou. (2022). Da Vinci Xi™ robot-assisted liver resection. *Intelligent Surgery*, *1*, 16–20. https://doi.org/10.1016/j.isurg.2021.10.001

Mulgan, T. (2019). Corporate Agency and Possible Futures. *Journal of Business Ethics*, *154*(4), 901–916. https://doi.org/10.1007/s10551-018-3887-1

Muscariello, L., Rosso, F., Marino, G., Giordano, A., Barbarisi, M., Cafiero, G., & Barbarisi, A. (2005). A critical overview of ESEM applications in the biological field. *Journal of cellular physiology*, *205*(3), 328–334. https://doi.org/10.1002/jcp.20444

Naidoo, S. (2021). *Biocompatibility Testing of Medical Devices*. Burlington: Arcler Press.

Nambu, T. (2016). Legal regulations and public policies for next-generation robots in Japan. *AI & SOCIETY*, 31, 483–500. https://doi.org/10.1007/s00146-015-0628-1

Neuman, Keir C., Nagy, Attila. (2008). Single-molecule force spectroscopy: optical tweezers, magnetic tweezers and atomic force microscopy. *Nature Methods*, *5*(6), 491–506.

Norasi, Hamid, Tetteh, Emmanuel, Law, Katherine E., Sid, Ponnal, Hallbeck, Susan, & Tollefson, Matthew. (2022). Intraoperative workload during robotic radical prostatectomy: Comparison between multi-port da Vinci Xi and single port da Vinci SP robots. *Applied Ergonomics*, *104*, 103826. https://doi.org/10.1016/j.apergo.2022.103826

Palmerini, E., Bertolini, A., Battaglia, F., Koops, B.-J., Carnevale, A., & Salvini, P. (2016). RoboLaw: Towards a European framework for robotics regulation. *Robotics and Autonomous Systems*, *86*, 78–85. https://doi.org/10.1016/j.robot.2016.08.026

Qi, Hu, Teng, Ma, Qi, Zhang, Jimin, Wang, Ye, Yang, Feiyan, Cai, & Hairong, Zheng. (2021). 3-D Acoustic Tweezers Using a 2-D Matrix Array With Time-Multiplexed Traps. IEEE *Transactions on ultrasonics, ferroelectronics, and frequency control*, *68*(12), 3646–3653. https://doi.org/10.1109/TUFFC.2021.3098191

Rong, Liu, Guo-Dong, Zhao, Wen-Bo, Zou, Xiu-Ping, Zhang, Shuai, Xu, Yang, Wang, Yan-Zhe, Liu, Yuan-Xing, Gao, Zhi-Peng, & Zhoua, Yu-Yao Song. (2022). Single-port robot-assisted hepatic left lateral sectionectomy using the da Vinci SP® system: A case report. *Intelligent Surgery*, *2*, 6–9. https://doi.org/10.1016/j.isurg.2022.02.002

Rothemund, P. W. (2006). Folding DNA to create nanoscale shapes and patterns. *Nature*, *440*(7082), 297–302. https://doi.org/10.1038/nature04586

Shi, C., Luu, D. K., Yang, Q., Liu, J., Chen, J., Ru, C., Xie, S., Luo, J., Ge, J., & Sun, Y. (2016). Recent advances in nanorobotic manipulation inside scanning electron microscopes. *Microsystems & nanoengineering*, *2*, 16024. https://doi.org/10.1038/micronano.2016.24

Suulker, C., Skach, S., & Althoefer, K. (2022). Soft Robotic Fabric Actuator With Elastic Bands for High Force and Bending Performance in Hand Exoskeletons. *IEEE Robotics and Automation Letter*, *7*(4), 10621–10627. https://doi.org/10.1109/LRA.2022.3194883

Sweeney, Aldrin. (2020). Incorporating NBIC social/ethical issues into STEM teacher education programmes. *Canada-Caribbean Institute Journal*, *1*(1): Proceedings of the Canada-Caribbean Research Symposium. Canada-Caribbean Institute. Brock University Open Journal System. 2020. https://journals.library.brocku.ca/index.php/cancarib/article/view/2369#

Taherkhani, S., Mohammadi, M., Daoud, J., Martel, S., & Tabrizian, M. (2014). Covalent binding of nanoliposomes to the surface of magnetotactic bacteria for the synthesis of self-propelled therapeutic agents. *ACS Nano*, *8*(5), 5049–5060. https://doi.org/10.1021/nn5011304

Vale, Daniel, El-Sharif, Ali, & Muhammed, Ali. (2022). Explainable artifcial intelligence (XAI) post-hoc explainability methods: risks and limitations in non-discrimination law. *AI and Ethics*, *2*, 815–826. https://doi.org/10.1007/s43681-022-00142-y

Villa, K., & Pumera, M. (2019). Fuel-free light-driven micro/nanomachines: artificial active matter mimicking nature. *Chemical Society Reviews*, *48*(19), 4966–4978. https://doi.org/10.1039/C9CS00090A

Wan, M., Liu, Z., Li, T., Chen, H., Wang, Q., Chen, T., Tao, Y., & Mao, C. (2021). Zwitterion-Based Hydrogen Sulfide Nanomotors Induce Multiple Acidosis in Tumor Cells by Destroying Tumor Metabolic Symbiosis. *Angewandte Chemie International Edition*, *60*(29), 16139–16148. https://doi.org/10.1002/anie.202104304

Wang, H., & Pumera, M. (2015). Fabrication of Micro/Nanoscale Motors. *Chemical Reviews*, *115*(16), 8704–8735. https://doi.org/10.1021/acs.chemrev.5b00047

Wang, Joseph, & Wei, Gao. (2012). Nano/Microscale Motors: Biomedical Opportunities and Challenges. *ACS Nano*, *6*(7), 5745–5751.

Wang, Qing, Shuhan, Chen, Jia, Zhou, & Antoine, Riaud. (2022). *Laser-guided acoustic tweezers*. National Natural Science Foundation of China, State Key Lab of ASIC and System, Fudan University (pp. 1–18). https://arxiv.org/abs/2203.14497

Wenyan, Qiao, Linglin, Zhou, Zhihao, Zhao, Di, Liua, Shaoxin, Lia, Jie, Ana, Xinyuan, Lia, Yikui, Gao, Peiyuan, Yang, Jiaqi Liu, Zhong, Lin, Wang, & Jie, Wang. (2022). A self-powered vector motion sensor for smart robotics and personalized medical rehabilitation. *Nano Energy*, *104*, 1–10. https://doi.org/10.1016/j.nanoen.2022.107936

Xu, X., Saw, P. E., Tao, W., Li, Y., Ji, X., Bhasin, S., Liu, Y., Ayyash, D., Rasmussen, J., Huo, M., Shi, J., & Farokhzad, O. C. (2017). ROS-Responsive Polyprodrug Nanoparticles for Triggered Drug Delivery and Effective Cancer Therapy. *Advanced materials (Deerfield Beach, Fla.)*, *29*(33), https://doi.org/10.1002/adma.201700141

Xue, S. (2022). The Application of Virtual Metacognitive Network Model in Preschool Guiding Art Network Teaching, *6th International Conference on Intelligent Computing and Control Systems (ICICCS)* (pp. 672–675). https://doi.org/10.1109/ICICCS53718.2022.9788219

You, M., Chen, C., Xu, L., Mou, F., & Guan, J. (2018). Intelligent Micro/nanomotors with Taxis. *Accounts of Chemical Research*, *51*(12), 3006–3014. https://doi.org/10.1021/acs.accounts.8b00291

Yuan, K., Aftoni, A., & Çobanoğlu, Ö. (2020). The Effect of Problem-Based Learning Model and Blended Learning Model to Metacognitive Awareness as a Reflection Towards a New Normal Era. *Jurnal Pendidikan Teknologi dan Kejuruan*, *26*(2), 183–188. https://doi.org/10.21831/jptk.v26i2.32783

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Конфликт интересов

Автор заявляет об отсутствии конфликта интересов.

Финансирование

Исследование не имело спонсорской поддержки.

История статьи

Дата поступления – 8 сентября 2022 г.
Дата одобрения после рецензирования – 17 января 2023 г.
Дата принятия к опубликованию – 6 марта 2023 г.
Дата онлайн-размещения – 10 марта 2023 г.