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Article

Explore the Legal Challenges and Coping Strategies for the Development of New Biomedical Technologies

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Abstract: New biomedical technologies are examined in depth and the legal and ethical challenges they pose. Key issues such as gene editing, the application of artificial intelligence in the medical field, and the protection of biological information data are analyzed. At the same time, we also found that technological advances in the development of the enormous potential of biomedicine, but also raises a series of ethical and legal issues. To this end, the paper proposes a series of effective response strategies aimed at providing guidance to policy makers, researchers, and healthcare professionals to ensure the rational and safe application of new technologies. Solutions to these challenges are elaborated. When it comes to gene editing, the article stresses the responsibility of scientists not only to push the boundaries of technology, but also to ensure that edited genes are in the public interest and respect individual rights. To this end, strict regulatory mechanisms should be put in place to ensure that gene editing is carried out only in certain and ethical circumstances. Although AI technology has brought many conveniences to the medical field, it also involves data privacy protection, the transparency of the AI decision-making process, and the impact of AI on traditional medical models. Therefore, it is necessary to formulate corresponding regulations to regulate its application, ensure the fairness and transparency of AI decision-making, and promote its integration and development with traditional medicine. The importance of the protection of biometric data was also emphasized. In biomedical research, a large number of personal biological information data, such as genome and proteome, are often involved. This data should be effectively protected to prevent data leakage and misuse. To this end, it is necessary to strengthen data security measures and establish standards and norms for data sharing and utilization to ensure the rational use and protection of data.

Keywords: biomedical ethics; new biomedical technologies; legal challenges; coping strategies

1. Introduction

1.1. Research Background and Significance

With the rapid development of biomedical technology, the application scope of new biomedical technology is more and more extensive, and the ethical problems and legal challenges caused by it are more and more significant. As an important branch of the field of biotechnology, synthetic biotechnology offers new renewable manufacturing technologies that can be used for the regeneration of chemicals, materials, biofuels, and living cells within biosensors and logic systems. However, the development of this technology has also brought many legal issues, such as intellectual property protection, privacy protection, ethical review and regulation, and legal liability. [1]

Intellectual property protection is an important issue. The development and innovation of synthetic biotechnology requires a large amount of input, including government support and capital market input. [2] However, due to the complexity and uncertainty of intellectual property protection,

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many scientific researchers and technology companies, in order to protect their intellectual property rights and potential business interests, have set up protective measures for scientific and technological research activities that are highly secretive, low in transparency, and difficult to supervise and predict, making humanities and social sciences scholars with professional knowledge and public representatives unable to participate in the upstream scientific research decision-making process. Privacy protection is also an important issue. [3] As a kind of special information, the importance of gene is self-evident. However, the misuse of genetic information is bound to have a great impact on individuals and the society as a whole. Therefore, the development and use of genes should be limited to a reasonable scope stipulated by law to protect personal privacy and public interest. Ethical review and regulation are also crucial. Synthetic biotechnology has a wide range of applications, which can be used in bioengineering, computer-aided design, cloud experiments, automated experiments and gene combination. However, due to the complexity and uncertainty of synthetic biotechnology, effective ethical review and regulation of it is an extremely challenging task. The attribution of legal responsibility is also an important issue. The application of synthetic biotechnology may give rise to a series of legal problems, such as tort liability, contractual liability and so on. Therefore, it is of great significance to make clear the attribution of legal responsibility and formulate corresponding legal norms for the healthy development of synthetic biotechnology. [4]

1.2. Research Objectives and Methods

This study aims to explore the legal challenges of the development of new biomedical technology, analyze the international legal regulations of biomedical ethics, and put forward the legal countermeasures for the development of new biomedical technology in combination with China's actual situation. The methods of literature analysis and case study were used. [5]

First, we analyze the legal challenges to the development of new biomedical technologies. These challenges include intellectual property protection, clinical trial ethics, and data security. At the international level, the rapid development of biomedical technology has made the protection of intellectual property rights between countries increasingly prominent, especially for the protection of innovative biomedical technology. In addition, clinical trial ethics is also an important legal challenge, involving the protection of subjects' rights and interests, the analysis and comparison of risks and benefits, and the interpretation of minimum risks. Secondly, we analyze the international legal regulations of biomedical ethics. [6] These regulations include international conventions, the provisions of international organizations and the domestic laws of each country. For example, international conventions such as the Universal Declaration of Human Rights and the Universal Declaration on Biomedical Research Ethics play an important guiding role in the research and application of biomedical ethics. [7] At the same time, international organizations such as the World Health Organization (WHO) and the European Medicines Agency (EMA) have also formulated relevant biomedical ethical guidelines, which provide specific guidance for the research and application of biomedical technologies. Finally, combining with the reality of our country, we put forward the legal countermeasures for the development of new biomedical technology. These strategies include improving the legal system of biomedical ethics in China, enhancing the transparency and impartiality of ethical reviews, strengthening the protection of intellectual property rights, and improving the professional quality of ethical reviewers. At the same time, we also realize that due to the different ethical thoughts and theories based on ethical review, the social environment, cultural customs and beliefs behind ethical review and other substantive contents, ethical review in China must be combined with the realistic background of China's medical health and the performance characteristics of medical ethical issues, to conduct an attempt to localize ethical review, rather than to impose foreign rules and standards. [8]

In general, the development of new biomedical technologies has brought many legal challenges, and we need to conduct in-depth research and analysis of these challenges, and propose corresponding legal countermeasures. [9] Only in this way can we better protect the development of biomedical technology and at the same time protect the rights and interests of mankind.

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2. Overview of Biomedical Technology Development

2.1. Status and Challenges of Biomedical Technology

Biomedical technology refers to a series of science and technology using the knowledge and technology of biology, medicine, chemistry and other disciplines to study and solve diseases, promote health, prolong life and improve the quality of life. The development and application of these technologies have not only brought revolutionary changes to the medical field, but also had a profound impact on the ethical and legal aspects of human society.

The application fields of new biomedical technologies are increasingly wide, such as gene editing, cell therapy, artificial intelligence and so on. Among them, gene editing technology can precisely modify the specific target genes of the organism genome, providing new possibilities for medical research and treatment. Cell therapy aims to cure diseases by repairing or replacing diseased cells. [10] The application of artificial intelligence in the medical field, such as assisted diagnosis and personalized treatment, has brought new changes to medical practice. However, the development of these new biomedical technologies also raises a number of legal and ethical issues. First, the safety and effectiveness of gene editing technology raises questions about the protection and utilization of human genetic resources. Second, the application of technologies such as cell therapy and artificial intelligence may involve issues of personal privacy and data protection. In addition, the clinical application of new biomedical technologies, such as gene editing technology in clinical treatment of ethical and legal issues, also need to be discussed in depth. The legal challenges in the development of biomedical technology mainly include intellectual property protection, privacy protection, ethical review and supervision, and the attribution of legal responsibility. Therefore, we need to fully consider the legal and ethical factors in the development of biomedical technology, and formulate appropriate legal and ethical norms to ensure the safe, effective, fair and just application of new biomedical technology. At the same time, we also need to strengthen legal and ethical research to provide strong legal and ethical support for the development of new biomedical technologies. [11]

2.2. Classification and Characteristics of New Biomedical Technologies

New biomedical technologies mainly include gene editing, cell therapy, artificial intelligence and so on. These technologies have an important position in the field of biomedicine, and their rapid development is widely used in medical research and clinical treatment.

Gene-editing technology, such as CRISPR-Cas9, is a precise gene-editing tool that can precisely modify specific target genes in an organism's genome. This technology has the advantages of low cost, easy to use and high efficiency, lowering the threshold of gene pruning modification technology, and setting off a global upsurge in the development and application of gene editing technology. Cell therapy techniques, such as immune cell therapy, stem cell therapy, etc., use healthy cells to replace or repair defective or damaged cells in order to treat disease. [12] This treatment can effectively treat many diseases, such as cancer, autoimmune diseases, etc. Cell therapy technology is highly innovative and risky, and its safety, effectiveness, and ethical issues need to be strictly examined. The application of artificial intelligence technology in the biomedical field, such as medical image analysis, gene prediction, disease diagnosis, etc., can improve medical efficiency and reduce medical costs. However, AI technology also presents challenges such as data privacy, information security, and ethical issues. These new biomedical technologies are highly innovative, risky and uncertain, and their development and application are faced with a series of legal challenges. For example, the safety of gene editing technology, the ethical issues of cell therapy technology, and the privacy issues of artificial intelligence technology all need to be regulated and regulated in law. Therefore, we need to develop corresponding laws and regulations to meet these challenges. At the same time, we also need to continuously improve the legal system to adapt to the development of new biomedical technologies. [13]

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3. Legal Regulations and Implications of International Biomedical Ethics

In the international legal regulation of biomedical ethics, the main contents include the ethical norms of life science research, the protection of human genetic resources and the protection of individual rights in biomedical research. These international legal regulations of biomedical ethics provide beneficial enlightenment for the development of biomedical technology in China.

Our country should strengthen the ethical review and supervision. Ethical review is an important means of ensuring that biomedical research is carried out within an ethical and legal framework. China should learn from the successful international experience to establish and improve the ethical review system of biomedical research to ensure the compliance and safety of research. At the same time, the supervision of the ethical review system should be strengthened to prevent the abuse and misconduct of the ethical review. Our country should make clear the legal responsibility belongs. In biomedical research, there are many sensitive ethical issues and legal regulations involved. China should make clear the legal responsibility in biomedical research according to the international legal regulations on biomedical ethics, so that a fair ruling can be made according to the legal provisions when disputes occur. Moreover, our country should clearly protect human genetic resources. Human genetic resources are an important basis for biomedical research, and their protection is directly related to the ethical and legal compliance of biomedical research. China should learn from the international legal regulations of biomedical ethics, and clarify the principles and specific measures for the protection of human genetic resources to prevent their abuse and damage. In addition, China should protect individual rights in biomedical research. In biomedical research, the personal rights and privacy of participants are particularly important. China should draw lessons from the international legal regulations on biomedical ethics, and clarify the principles and specific measures of participants' rights protection to prevent them from being violated. China should draw useful inspiration from the international legal regulations of biomedical ethics, strengthen ethical review and supervision, clarify the attribution of legal responsibility, clarify the protection of human genetic resources, and protect individual rights in biomedical research, so as to ensure that the development of biomedical technology in our country is carried out within the moral and legal framework. [14]

4. Legal Regulation and Practice of Biomedical Ethics in China

The legal regulations of biomedical ethics in China mainly include the Measures for the Management of biomedical research Ethics and the Interim Measures for the Management of Human Genetic resources. In practice, China has also achieved some results, such as strengthening ethical review and supervision, and protecting human genetic resources. However, from the current legislation, China has adopted a weak protection attitude towards biotechnology achievements, which reflects the insufficient protection of biotechnology achievements in our country to a certain extent. [15] At the same time, China's supervision of ethical review is relatively simple, mainly for the review of research programs, research purposes and informed consent. There are many problems in the operation process and the establishment of rules and regulations of ethics committees. Ethics committees in some medical institutions only serve for the establishment of scientific research projects, and are virtually useless in the implementation of specific ethical management.

In order to improve the quality of medical clinical trial research and protect the rights and interests of subjects, research institutions must set up a strict ethical review system. China should learn from the Policy Statement on Human Research Ethics issued by the National Science Foundation of Canada, which has strict provisions on the subjects, ways and procedures of ethical review. [16] Strengthening the ethical review of medical research from the institutional and mechanism is also one of the fundamental purposes of formulating the clinical trial registration system. In addition, China needs to strengthen the legislation to protect the rights and interests of human genetic resources providers, establish the providers of genetic privacy, physical rights and other personal rights, and protect the rights of human genetic resources providers to rational use of biotechnology patents based on their genetic resources. In terms of management system, it is necessary to establish the management area and scope of genetic resources management

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departments, and in particular to define a clear management relationship for overlapping management of genetic resources; Clarify the conditions for the acquisition of genetic resources, the application and approval procedures, the management department and its specific responsibilities and powers. [17]

From the point of view of national biosecurity, the patent issues related to human genetic resources are mainly two aspects: ownership and information disclosure. The specific content has been analyzed above, and will not be repeated here. However, there is no further regulation on the patent disclosure of human genetic resources based on the existing patent law. The disclosure of the source of human genetic resources may lead to the disclosure of information involving state secrets and national security, and whether the disclosure of the source of such genetic resources will pose a threat to the biosecurity of our country. Therefore, China should further clarify the ownership of human genetic resources, information disclosure and other issues at the legal level to ensure the safety and stable development of our country in the field of biotechnology. At the same time, our country should actively participate in the research and formulation of international biomedical ethics laws, learn from the advanced experience of the world, and promote the development and improvement of our country's biomedical ethics laws. [18]

5. Legal Response Strategies for the Development of New Biomedical Technologies

The rapid development of biomedical technology has brought a lot of convenience to human beings, but also caused a series of legal problems. There is a close relationship between law and biomedical ethics, so it is of great significance to explore the legal challenges and countermeasures of the development of new biomedical technologies.

First of all, improving the legal system of biomedical ethics is an important measure to deal with the legal challenges of the development of new biomedical technologies. The law should clearly define the ethical principles of biotechnology research and application, clarify the boundaries of biotechnology research and application, and prevent the abuse of biotechnology. [19] At the same time, the law should improve the ethical review and supervision mechanism of biomedical research and application to ensure the safety and effectiveness of biomedical research and application. Second, strengthening the protection of intellectual property rights is an important strategy to cope with the development of new biomedical technologies. The innovation results of biomedical technology often have high economic value, so strengthening the protection of intellectual property rights can encourage researchers to carry out technological innovation, but also protect the legitimate rights and interests of innovation results. [20] Third, strengthening privacy protection is also an important strategy to cope with the development of new biomedical technologies. The application of biomedical technology often involves personal privacy, so strengthening privacy protection can protect the rights and interests of individuals and prevent the abuse of biotechnology. Fourth, improving the efficiency of ethical review and regulation is also an important strategy to cope with the development of new biomedical technologies. The more efficient the ethical review and regulation, the more timely the detection and treatment of the abuse of biotechnology, to ensure the safety and effectiveness of biomedical research and applications. Finally, clear attribution of legal responsibility is an important strategy to cope with the development of new biomedical technologies. Clear attribution of legal responsibility can effectively prevent the abuse of biotechnology and ensure the safety and effectiveness of biomedical research and applications. In conclusion, there is a close relationship between law and biomedical ethics, so it is of great significance to explore the legal challenges and countermeasures of the development of new biomedical technologies. Only by improving the legal system, strengthening the protection of intellectual property rights and privacy rights, improving the efficiency of ethical review and supervision, and clarifying the attribution of legal responsibility can we effectively deal with the legal challenges brought by the development of new biomedical technologies, and promote the healthy and sustainable development of biomedical technologies. [21]

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6. Conclusion

This paper mainly discusses the relationship between law and biomedical ethics in the development of new biomedical technologies, and puts forward effective strategies to deal with legal challenges. Firstly, this paper points out that the development of new biomedical technologies provides new possibilities for medical research and treatment, but also brings many legal problems. Among them, gene as a special information, its protection is particularly important to discuss. Next, this paper analyzes the protection of genetic information in detail, and puts forward two possible protection methods in civil law: privacy and intellectual property rights. In the protection of genetic information, the protection of privacy is mainly reflected in the protection of personal genetic information to prevent its abuse or infringement. The protection of intellectual property rights is mainly reflected in the protection of genetic technology achievements to prevent them from being copied or infringed. However, how to implement these protective measures is still a question worthy of further study.

In addition, the role of criminal law in the development of biomedical technology is also discussed. Although patients can justify certain violations by exercising their right to make decisions, such decisions are not omnipotent, especially when it comes to human dignity, criminal law still needs to intervene. Finally, this paper proposes effective strategies to deal with the legal challenges of biomedical ethics. It includes improving the legal system of biomedical ethics, strengthening the protection of intellectual property rights, strengthening the protection of privacy rights, improving the efficiency of ethical review and supervision, and clarifying the attribution of legal responsibility. The implementation of these strategies will help address the legal challenges arising from the development of new biomedical technologies.

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