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Analysis and Consideration of Legal Issues Related to Stem Cell Therapy

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Abstract: Stem cell therapy has gained momentum in recent years and has positively and innovatively impacted the biomedical field. This paper uses a comprehensive literature analysis and comparative methodology to compare the differences in the development and regulatory systems of stem cell therapies in the UK and China through the available references. The legal framework for stem cell therapies is more complete in the UK, and the government has invested in a regulatory system that promotes research and development. By contrast, China has had problems with surveillance confusion in the past. In recent years, it has worked to standardize the development of therapies and strengthen the regulatory system. While both countries are improving their censorship, some challenges remain. Based on the challenges analyzed, this paper intends to provide suggestions to those involved in stem cell therapies to develop better in the future.

Keywords: stem cell therapy, legal framework, regulatory

1. Introduction

As biomedicine evolves, stem cell therapy emerges as a potential medical innovation. Stem cell therapy refers to enhancing the body's repair mechanism by stimulating and regulating stem cell populations aiming to achieve a steady state of regenerative stem cells and self-repair [1]. The practice of this therapy dates back as far as the nineteenth century and spans multiple therapeutic areas. Instances include regenerative medicine, cancer treatment and immunotherapy [2]. Not only does it involve the medical promise of innovative technology, but it also faces many challenges at the ethical and legal levels. The aim is to achieve sustainable development in this field under a responsible, ethical framework and standardization [3].

This paper will analyse and reflects on the legal issues related to stem cell therapy, based mainly on the positions and differences within the legal frameworks of the UK and China, it will explore the role of clinical trials and regulatory surveillance in the legitimate fences and the legal safeguards for patients. This paper will use a comprehensive literature analysis and comparison method to compare and research each country's regulations, standards, and practice cases to discover the problems and challenges and explore some suitable solutions. Hence, the significance of this paper is to provide an in-depth legitimate understanding of scientists, doctors, patients, and practitioners in stem cell therapy. According to analyse of the framework, risk and patients' rights will provide concrete legal guidance and suggestion for promoting the sustainable development of stem cell therapy.

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2. Legal framework for stem cell therapy.

2.1. The United Kingdom: legislation, regulation, and implement

The potential benefits of stem cell therapy justify innovation and research. In the UK, researchers are struggling to harness the resources and capabilities to develop the treatment, and the British government is keen to work to ensure that the UK is a leader in this field [4]. For example, in 2004, the UK public sector invested over £15 million in research into stem cells and established relevant departments to develop long-term research and strategies [4]. Thus, to respond to the development of scientific research on therapies, the UK's laws have been gradually improved to provide consistency and clarity.

The regulation of stem cell therapy research from the laboratory to the clinic is cautious and cumbersome, and it is essential to manage scientific progress in a way that does not overlap with the regulatory duties of each sector and citizens have trust that their interests will be protected [4]. Firstly, in terms of regulatory and ethical frameworks, the UK Parliament voted to approve research into stem cell treatments in the early years. A select committee was set up to discuss and confirm that there is a solid medical and scientific case for research into therapies for various diseases [5]. For example, treatment for chronic diseases: Alzheimer's and diabetes [5]. These diseases are being used as the basis for research into treatments. Indeed, these actions span several regulatory areas: concerning the need to obtain permission from NHS Trust to participate in clinical trials and establish a special health authority to protect the interests of patients [5]. Moreover, from a researcher's perspective, there are several organizations to which a researcher may need to apply to seek a license [5]. For example, an application was made to obtain accreditation from the National Auxiliary Medical Service (NAMS), followed by the UK's independent regulator of fertility treatment and research using human embryos (HFEA) and the Health Technology Assessment (HTA). The purpose of the license is for ethical surveillance. This is followed by sectoral applications involving other detailed regulatory censorship [5]. Thus, these regulatory measures encompass inspections of independent organizations, health research and personnel. The whole process is cumbersome and complex.

2.2. China: regulatory framework, censorship, and progress

In recent years, stem cell therapy has been actively developed in China. China's research and regulation of therapies officially began to be implemented in 2015 [6]. Like other countries, China has been researching stem cell therapies for over a decade, and regulatory concepts have been developing for over 30 years. Many diseases and unmet medical needs have fueled the potential and expectation of therapies [6]. As early as the 1990s, therapies were first introduced to the regulatory authorities, which categorized cell and gene therapies under the scope of the Drug Administration Law and allowed clinical trials after review [6]. However, there is a need for more scientific evidence therefore, the ability to demonstrate therapies' safety and clinical benefits. At the same time, many healthcare organizations are secretly treating patients with unproven stem cell therapies to avoid regulatory scrutiny, resulting in the inability to conduct rigorous clinical trials, which are often required [6]. Unproven commercial stem cell therapies exist in many countries, including China and the United States [7]. Subsequently, to regulate this confusion, the Chinese Ministry of Health proposed a moratorium on stem cell clinical research and treatment, with a one-year focus on reviewing and correcting unproven stem cell therapy applications.

Furthermore, China has strengthened its regulatory policies since 2015. The National Health Planning Commission (NHPC) and the State Food and Drug Administration (FDA) jointly contributed to academic and ethical committees. They published relevant documents to provide technical support and ethical guidance for clinical research. They authorized tertiary hospitals to

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perform primary review assessments and detailed rules for local stem cell applications [7] which means that a new era of supervision of stem cell therapies has officially begun in China. Relevant data show that at the end of 2020, more than 100 healthcare organizations have successfully registered for stem cell clinical research. More than half of China's provinces, such as Beijing, Shanghai, and Guangdong, carry out registrations [6]. In addition, the Chinese government applies regulations and a dual regulatory system to stem cell research programs.

On the one hand, it restricts the entry of unproven stem cell treatments into medical institutions. On the other hand, it highly restricts three hospitals from entering clinical practice [7]. Therefore, compared to the unsafe and unproven treatments in the previous years, the research and regulation of stem cell therapies in China has made some progress and is still improving.

2.3. Differences in regulation between the UK and China

In the UK, the function and scope of the censorship of stem cell therapy include sharing resources and information, as well as working with other regulatory authorities to rationalize and reduce the burden of information gathering and verification processes on the regulator and to efficiently safeguard the proper functioning of the regulation [5]. Moreover, the government supported the development of therapies. It was supported by early investment and the establishment of research departments focusing more on development strategies. The legal framework has been gradually improved to meet regulatory and ethical requirements and ensure scientific development. As a result, there is more consistency and clarity in the regulatory measures taken in the UK.

By contrast, there may have been regulatory confusion in China, leading to many unproven treatments being performed by healthcare organizations to avoid regulation [7]. However, in recent years, regulatory policies have been strengthened, technical and ethical regulations have been established, and research and regulatory bodies have been set up. At the same time, China has also adopted restrictive measures to regulate clinical trials. Although China and the UK constantly try to improve the regulatory system according to their national conditions, many challenges still exist.

3. Legal Challenges to Stem Cell Therapy

3.1. Legal challenges to stem cell therapy in the UK

Although the UK currently has a relatively complete regulatory system for stem cell therapies, several issues and challenges have arisen as the science evolves. The problem arises from balancing research needs with professional and patient regulatory autonomy [8], meaning that research, clinical trials and the development of new stem cell therapies seek new treatments to improve patients' health. Patients consent to participate in clinical trials, their choice of treatment options, and the protection of their personal health information.

Secondly, patients and their families treat stem cell therapy as their only hope. Therefore, in some cases, it will contribute to developing unproven therapies and encourage patients to undergo treatment [9]. For example, a public hospital in Italy was monitored for the use of therapies for patients who did not comply with Italian regulations, and the government subsequently issued an injunction. This ban then resulted in many sick families being unable to access treatment. However, access to treatment was restored through judicial decisions [9]. In this case, due to public opinion, the rules established for patients' safety were used as an obstacle to access to treatment. Thus, it shows that the management of stem cell therapy is challenging, especially in the face of desperate patients seeking help while at the same time being confronted with unproven therapies that are susceptible to hope and acceptance [9]. However, this behaviour is unjustified from an ethical point of view, and the relaxation of the regulatory system would hinder the development of safe treatments.

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3.2. Legal challenges to stem cell therapy in China

In China, the regulatory system for stem cell therapies has largely cleaned up the therapeutic environment since it was standardized in 2015. However, several challenges still arise that may affect the development. In 2019, the National Health and Health Commission issued a draft of opinions related to clinical research on somatic cell therapy, aiming to allow for the safe entry of clinical treatments after a rigorous review. However, relevant researchers are concerned about whether the current governance model in China may interfere with innovation and research in stem cell therapy [7]. Moreover, whether the dual-regulation supervisory policy mentioned above may restrict medical clinics from offering stem cell therapy in the future and whether local healthcare organizations have a clear responsibility to curb the incidence of unproven stem cell therapy [7]. The reason for this is the emergence of many 'stem cell tours' aimed at travelling to regions and countries where the treatment is feasible for unsafe treatment [10]. In addition, a significant factor in the repeated adjustment of stem cell therapy interventions in China is the lack of laws specifically addressing the use of stem cells [7]. Thus, suggesting that the legality of the presence of stem cells is in a grey area.

4. Discussion: constructive legal advice on the above challenges

The possible solutions to the above challenges could be the following. Firstly, problems may arise from balancing research needs with professional and patient regulatory autonomy in the UK [8]. It could be aimed at doctors to adopt more explicit guidance and education on monitoring the treatment process [11], to make them more accountable for the treatment, and to institutionalize unique contact plans to avoid too much information leakage to safeguard patient autonomy [8]. Moreover, when necessary, it is possible to carry out regulatory work across jurisdictions, for which an information network is created to obtain a higher quality of consistency and clarity [8]. In addition, in response to the possibility of unproven cellular therapies [9], perhaps the solution is to view stem cell therapies as a shared responsibility and to ethically guide stakeholders such as researchers, physicians, lawyers, governments, and patients to work together for this purpose to maximize the development and regulation of therapies [9]. From a regulatory perspective, regulations need to ensure the ethical nature of the industry and patient safety without restricting the positive development of the industry [11].

There are possible solutions that China faces challenges: first, it may be possible to use a more flexible approach to regulation and development to avoid curbing research and constraints on therapies. An example is unregulated privileges for patients with serious diseases [7]. For those concerned about the two-track regulatory policy to curb development and the responsibility of local healthcare organizations, local committees may function as advisors to discuss issues promptly and effectively [7]. In addition, it may be necessary to gradually establish special regulations for positive development and violation of the law. For example, warnings and penalties for unproven stem cell treatments and strict regulation of unsafe “stem cell tourism treatments”. These possible scenarios can help enhance stem cell research development and industrial marketization in China [7]. National and international cooperation is necessary if long-term and stable development in stem cell research is to be achieved, and this aspect will probably be accomplished under the leadership of the World Health Organization and other agencies [3]. Therefore, whether in the UK, China, or even other countries, the research and development of stem cell therapies requires active cooperation and regulation from various industries.

5. Conclusion

In summary, the legal framework for stem cell therapies continues to improve and develop in countries such as the UK and China. However, challenges still need to be addressed, such as balancing

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research needs with patients' regulatory autonomy, restricting unproven treatments, and implementing inadequate regulations. The UK is committed to promote scientific research and development through positive investment and established a regulatory system, while China has made some progress in regulating the development of therapies. Suggestions to face the challenges are to strengthen transnational cooperation, develop more flexible surveillance, and promote cooperation and communication between countries. The limitation of this paper is that more discussion on stem cell therapy is focused on clinical treatments and cases. There is relatively little discussion on the legal level, and some actual legal examples still need to be included. Thus, the paper could be more comprehensive in exploring the aspects. According to continuous development of therapy, there will be multiple discussions, especially regarding the legal and social-ethical aspects, and new debates may emerge in the future.

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