

Legal and Ethical Void in the Implementation of Stem Cell Technology in Indonesia

Lia Marlina, Evita Isretno Israhadi

Universitas Borobudur, Indonesia

lm.marjono@gmail.com, evita_isretno@borobudur.ac.id

ABSTRACT

This study examines the legal gaps and ethical challenges in stem cell technology utilization in Indonesia. Stem cell technology in embryonic stem cells offers great potential in the medical field but also faces controversies and complex regulatory issues. The study identifies the legal gaps in current regulations and their impact on legal certainty for researchers, medical practitioners, and patients. It also analyzes the limitations of existing rules and proposes legal reformulation to address rapid technological developments and emerging ethical issues. The methodology in this study uses normative legal methods with legislative and analytical approaches to evaluate regulations related to stem cells in Indonesia. The findings of this study are expected to guide effective regulatory reform to support safe and ethical innovation of stem cell technology in Indonesia. It concludes that the legal void in stem cell technology regulation creates challenges such as uncertainty for stakeholders, security and ethical risks, and hindered research progress, necessitating comprehensive legal reform to establish clear guidelines, update security standards, integrate ethics, ensure transparency, and align with international standards to support safe innovation and protect public welfare.

Keywords : legal gap; stem cell ethics; medical innovation

INTRODUCTION

The development of science and technology is now increasingly rapid, along with the increasing human need for discoveries that can meet the needs of life and improve welfare. Initially, science aimed to find the truth, while technology was created to meet the needs and improve the quality of human life (Asbar & Wijaya, 2021). In the modern era, technological developments are increasingly widespread thanks to the extensive information network, which supports the discovery of cutting-edge innovations in various fields, including medicine. One important breakthrough in the medical field is the use of stem cells, which offer solutions to improve the quality of treatment and health, as well as provide better health insurance for the community (A'la Al Maududi, 2014).

Stem cells are cells with the unique ability to divide and differentiate into various types of cells with specific functions (Tursina, 2019). There are several types of stem cells based on their abilities: totipotent, which can develop into all types of embryonic cells and tissues; pluripotent, which can form cells from all three germ layers; multipotent, which can produce various kinds of specific cells in certain tissues; and unipotent, which can only differentiate into one type of particular cell. Stem cells have great potential in treating various diseases, such as bone and heart disease, and are considered an innovative solution to improve public health. With the development of stem cell-based treatment methods, it is expected to enhance the quality of health, which is a fundamental human right (Sagita, 2020).

Stem cells offer a potential solution in treating various diseases, including bone and heart or other diseases. In the medical world, developing stem cell-based treatment methods is considered an important step to improve the quality of public health. Advances in stem cell therapy are expected to provide better health outcomes because health is a fundamental aspect of human life and is a basic right that must be maintained and promoted by all parties. Stem cells application is expected to help treat various medical conditions, provide new hope for patients, and improve their quality of life (Afriko, 2016).

In Indonesia, health is one of the national goals stated in the Preamble to the 1945 Constitution of the Republic of Indonesia, which emphasizes the importance of advancing general welfare and improving the national life (Sulastri, Aryanti, & Satino, 2020). Comprehensive and sustainable national development, including in the health sector, is expected to increase awareness, willingness, and ability to live healthily for every citizen (Notoatmodjo, 2010). By focusing on health as a national priority, it is hoped that a healthier and more prosperous society will be achieved, in line with the goals of the constitution and efforts to improve the quality of life (Susanti & Sari, 2021).

In Indonesia, the government has regulated various aspects related to the use of stem cells through several relevant legal regulations. One of the main regulations is Minister of Health Regulation Number 32 of 2014, which designates certain hospitals as centers for medical services development, research, and education for tissue banks and stem cells (Slabbert & Venter, 2021). This regulation aims to regulate health institutions that play a role in the development and application of stem cell technology. In addition, Minister of Health Regulation Number 50 of 2012 restrains the organization of stem cell processing laboratories for clinical applications, ensuring that facilities handling stem cells meet certain standards for safety and effectiveness (Zhang et al., 2012).

Indonesia has also issued additional regulations to regulate stem cell treatment methods in more detail. Ministerial Regulation Number 32 of 2018 rules the provision of stem cell services, while Ministerial Regulation Number 63 of 2013 regulates the provision of tissue or cell banks (Dewi, Nasser, Buaton, & Lumbuun, 2022). These regulations provide a clear legal framework for the use of stem cells, both in medical and research contexts. With these regulations, Indonesia has established a strong legal basis to protect citizens in terms of the use of stem cell treatment methods, as well as ensuring that the practice is carried out by applicable standards (SAPUTRA, 2022).

Although legal regulations related to the use of stem cells in Indonesia already exist and are quite comprehensive, there are still significant problems in the aspect of health ethics that indicate a legal vacuum. One of the main issues is the inadequacy of regulations governing the ethical dilemmas that arise from the use of stem cells, especially in terms of the use of embryonic stem cells. Many people still have concerns about the moral implications of the use of stem cells derived from embryos, especially related to the rights and status of the embryo (Peng, Huang, & Zhou, 2020).

This legal vacuum has the potential to create uncertainty and differences in interpretation in the field, which can affect the implementation and clinical practice related to stem cells. For example, although there are regulations governing the organization of laboratories and hospitals, there are no clear guidelines regarding ethical boundaries in stem cell research and clinical applications, especially those related to moral principles and human rights. It can lead to inconsistent or even controversial practices that not only have the potential to harm patients but can also cause public distrust of this technology (Sari, Santosa, & Winata, 2024).

In addition, this vacuum also includes the lack of effective supervision and law enforcement related to the ethical aspects of stem cell use. The lack of specific regulations can result in differences in standards between different health facilities and research institutions, creating problems in ensuring that all practices comply with generally accepted ethical principles (Rif'ati, 2012). Therefore, there is an urgent need to formulate and implement more comprehensive and specific regulations on the ethical aspects of stem cell use to ensure that the development of this technology can be carried out with full consideration of moral values and human rights.

Despite the existing regulations addressing stem cell technology in Indonesia, significant legal and ethical challenges remain. While international studies have explored the balance between technological advances and ethical considerations, Indonesia faces unique issues due to a lack of comprehensive and specific legal frameworks. The ethical dilemmas, particularly those involving embryonic stem cells, remain underexplored in the Indonesian context, where cultural, religious, and social values heavily influence public policy. Current regulations inadequately address the nuances of these ethical concerns or provide clear guidelines for implementation. This research fills the gap by examining the intersection of legal voids and ethical challenges, offering context-specific insights into the regulatory deficiencies and their implications for medical innovation in Indonesia.

The rapid advancement of stem cell technology globally underscores the urgent need for Indonesia to establish comprehensive and updated regulations. As this technology offers groundbreaking solutions for degenerative diseases and life-threatening conditions, unclear legal and ethical frameworks can hinder its safe and ethical implementation. Without immediate regulatory reform, Indonesia risks lagging behind international standards, potentially losing opportunities for global collaboration and innovation. Moreover, the absence of clear guidelines could lead to unethical practices, jeopardizing patient safety and public trust in medical advancements. The urgency lies in creating a framework that aligns with international norms while addressing local ethical and societal concerns.

This research introduces a unique perspective by focusing on the interplay between regulatory gaps and ethical dilemmas specific to Indonesia's socio-cultural and legal context. Unlike prior studies, which predominantly discuss the scientific potential or ethical challenges of stem cell technology in general, this study critically evaluates Indonesia's regulatory framework in detail. It proposes a tailored legal reform that integrates ethical principles, patient safety, and international standards, considering Indonesia's unique cultural and religious values. The novelty lies in its dual approach of addressing both the technical legal void and the underlying ethical controversies, creating a blueprint for inclusive and contextually relevant policy-making.

The primary objective of this research is to analyze the legal and ethical gaps in stem cell technology regulation in Indonesia and propose comprehensive reformulations to ensure safe and ethical application. The findings aim to provide actionable recommendations for policymakers to bridge the existing regulatory voids and establish robust oversight mechanisms. This study benefits medical practitioners by offering clear guidelines for implementing stem cell technology and protecting patients from unethical practices. It also contributes to advancing Indonesia's position in global medical research, ensuring that ethical considerations are integrated into scientific progress while safeguarding public welfare.

RESEARCH METHOD

The normative legal research methodology in this study uses a legislative approach and an analytical approach to evaluate regulations related to stem cells in Indonesia. The legislative approach by analyzing various legal regulations governing the use of stem cells, such as Permenkes Number 32 of 2014 and Permenkes Number 50 of 2012, to understand the existing legal framework and identify gaps and potential ethical issues. Meanwhile, the analytical approach is used to assess and criticize the effectiveness and consistency of these regulations in addressing emerging ethical and legal issues to provide recommendations for more comprehensive policy improvements and adjustments.

RESULT AND DISCUSSION

Regulation of the Use of Stem Cell Technology in Existing Law in Indonesia

The use of embryonic stem cells in medical practice offers great potential for the treatment of various degenerative diseases such as neurological, heart, and liver diseases. Embryonic stem cells can also provide additional benefits, such as helping to understand the mechanisms of disease and reducing the need for laboratory animals and direct human drug testing. However, the development of this technology has sparked widespread debate in the medical world, especially regarding the ethics and legal status of embryos. Removing stem cells from an embryo involves damage to the embryo, which ends in its death. It raises significant ethical questions, especially regarding the moral status of the embryo. Some argue that embryos should be treated on a par with humans because of their potential to develop into humans. Others debate that embryos are simply living tissue that has not yet fully developed.

This debate includes whether a developing embryo should be considered a living being or simply a potential to become a human being. This debate highlights the major challenges in regulating the use of embryonic stem cells in positive law. There is disagreement about how embryos should be treated ethically, and how this affects biomedical practice and research. While the development of this technique represents a cutting-edge advancement in the biomedical field, ethical issues regarding the status of embryos require careful attention to ensure that this technology is used in responsiveness and by widely recognized moral principles.

The regulation of stem cells in Indonesia is comprehensively regulated through several legal regulations that aim to regulate the use and practices related to stem cells in a medical context. One of the main regulations is Law Number 36 of 2009 concerning Health, which provides a basic framework for health policy in Indonesia, including the regulation of advanced medical technologies such as stem cells. The law sets out general principles on how medical technology should be applied to ensure its safety and effectiveness in health services. To more specifically regulate medical services involving stem cells, Permenkes Number 833 of 2009 was issued. This regulation regulates the implementation of stem cell medical services in detail, including operational standards and procedures that must be adhered to by health facilities. Decree of the Minister of Health Number 834 of 2009 also serves as a guideline for the implementation of stem cell medical services, which provides further details on the implementation and management of these services.

In addition, Minister of Health Regulation Number 50 of 2012 regulates the organization of stem cell processing laboratories for clinical applications. This regulation establishes technical and procedural standards that must be followed by laboratories in processing and using stem cells for clinical therapy, ensuring that all processes meet

established safety and quality standards. Minister of Health Regulation Number 32 of 2014 establishes hospitals as centers for medical services, research, and education for tissue and stem cell bank development. This regulation defines which hospitals are recognized as development centers in terms of stem cell research and applications, and establishes their roles in the development and application of this technology. These regulations as a whole aim to ensure that the use of stem cells is carried out in a safe, effective manner, and accordance with applicable ethical and legal standards.

In Indonesia, the use of embryonic stem cells is strictly regulated and expressly prohibited, as stipulated in the Decree of the Minister of Health Number 834 of 2009. This regulation covers various aspects related to stem cell services, including specific regulations on the types of stem cells that can be used. One important point of the decree is the regulation regarding embryonic stem cells, where pluripotent and totipotent embryonic stem cells are explicitly prohibited from being used. The Decree of the Minister of Health Number 834 of 2009 stipulates in the definition of stem cell services letter B, that the use of embryonic stem cells—which can develop into various types of cells and tissues in the body—is not permitted. This prohibition is based on ethical reasons related to human dignity. Point 5 in the philosophy of the decree states that the use of embryonic stem cells can interfere with human dignity, reflecting moral concerns regarding the status and treatment of embryos.

Law of the Republic of Indonesia Number 36 of 2009 concerning Health regulates various important aspects related to the use and management of stem cells. Based on Article 66, cell transplantation, whether from humans or animals, may only be carried out after confirmed safe and beneficial. This emphasizes the need to ensure that each transplant procedure meets safety and effectiveness standards before being implemented in medical practice. Article 67 regulates the collection and delivery of specimens or body parts, which may only be carried out by health workers who have the appropriate expertise and authority, and must be carried out in certain healthcare facilities. Further provisions regarding the requirements and procedures for the collection and delivery of these specimens must comply with applicable laws and regulations. This aims to ensure that the procedures for the collection and delivery of body organs are carried out with professional standards and by the law.

In Article 70, this law regulates the use of stem cells with special provisions. This article states that stem cells may only be used to cure diseases and restore health, and are prohibited for reproductive purposes. In addition, the use of embryonic stem cells is prohibited altogether. To regulate further details regarding the use of stem cells, including provisions on the use of embryonic stem cells, will be regulated in the Minister of Health's regulation. The regulation aims to ensure that the use of stem cells is carried out ethically and by legitimate medical purposes, while protecting applicable moral and legal principles.

In the regulation and implementation of stem cell technology in Indonesia, various government agencies and regulatory bodies play a key role in ensuring compliance with the regulations and standards set. The Ministry of Health of the Republic of Indonesia is the main institution that regulates policies and regulations related to stem cells, including the issuance of regulations such as the Permenkes on the implementation of stem cell services and stem cell processing laboratories. The Ministry of Health is responsible for establishing guidelines, standards, and procedures that must be followed by all parties involved in the use and research of stem cells. In addition, institutions such as the Food and Drug Supervisory Agency (BPOM) also play an important role in the supervision and

regulation of stem cell technology, especially related to products used in therapy and research. BPOM ensures that all stem cell products on the market meet safety and effectiveness standards before obtaining a distribution permit.

Hospitals, laboratories, and other health institutions have significant responsibilities in implementing stem cell regulations. Hospitals designated as centers for medical services development and stem cell research must comply with the guidelines set by the Ministry of Health. They are responsible for carrying out clinical procedures by following applicable standards and ensuring that all stem cell practices are carried out by legal and ethical provisions. Laboratories that process stem cells also have an important role in ensuring that the processing process and clinical applications comply with established regulations. Laboratories must meet technical and operational standards stipulated in regulations such as the Minister of Health Regulation on the implementation of stem cell processing laboratories. They are also responsible for ensuring that all processes are carried out with a high level of safety and quality.

In the regulation of stem cell technology in Indonesia, there are several legal gaps and limitations in regulations that need to be identified and analyzed. One significant legal gap is the lack of specific regulations regarding the ethical aspects of the use of embryonic stem cells. Although there is a general prohibition on the use of embryonic stem cells in several regulations, such as the Decree of the Minister of Health Number 834 of 2009, the regulation does not deeply regulate the ethical debate regarding the moral status of embryos and how this issue should be addressed in clinical practice and research.

Another limitation is the lack of clear guidelines on procedures and standards for stem cell research and use in a broader context. Existing regulations tend to focus more on technical and operational aspects, without providing sufficient detail on how to balance scientific progress with ethical and human rights considerations. For example, although there are regulations on the processing and use of stem cells, there are no provisions that explicitly address issues related to ethical decisions that must be made by researchers and medical practitioners.

Gaps in regulations are also evident in oversight and enforcement. Although there are regulations governing the use and research of stem cells, oversight and enforcement mechanisms are often unclear or ineffective. It can lead to differences in the application of standards across facilities and institutions and pose risks related to regulatory compliance. These limitations include the lack of a comprehensive system for monitoring and assessing regulatory compliance, as well as the lack of clear sanctions for violations.

The use of embryonic stem cells in medical therapy has raised significant controversy, particularly because it involves the destruction of human embryos to isolate stem cells. This controversy arises because the harvesting stem cells from embryos is often carried out in the early stages of development, namely between days 5 and 7 after fertilization. At this stage, the embryo has not yet attached itself to the uterine wall and in the early stages of human life development. The destruction of embryos to obtain stem cells is considered by some to be a violation of human ethics and religious law, because it is considered an act that destroys the potential for life.

Some argue that even though the embryo is in the early stages of development, it still has the right to live and develop, similar to the rights given to humans who have been born. This controversy debates the moral status and rights of embryos in the context of the use of stem cell technology. This opinion reflects the concern that such actions could be considered an affront to human dignity, because embryos are considered in early forms of life that deserve to be treated with respect.

These ethical issues often conflict with the principles of religious law and morality, which assume that human life begins in the early stages of embryonic development. As a result, there are challenges in balancing scientific and technological advances with ethical and legal considerations. The development and application of embryonic stem cell technology requires careful consideration of its impact on human rights and prevailing moral values in society.

The Impact of Legal Vacuum and the Urgency of Legal Reformulation on the Use of Stem Cell Technology

In the rapid development of stem cell technology, the legal vacuum in regulations in Indonesia poses various challenges and significant impacts. Stem cell technology, which offers revolutionary potential in the treatment of various diseases, faces regulatory vacuums that can hinder scientific progress, pose risks to patients, and create legal uncertainty for medical practitioners and researchers. The lack of clarity in the regulations regarding the use of stem cells, particularly embryonic stem cells, indicates the need for a comprehensive legal reformulation to address existing gaps. The urgency of this reformulation is not only aimed at improving legal and ethical aspects, but also to ensure that stem cell technology can be applied safely and effectively, in accordance with international standards and applicable moral principles.

Legal certainty in stem cell technology usage is essential to ensure that research and therapy are conducted safely, ethically, and by applicable regulations. Legal gaps in stem cell regulations can create significant legal uncertainty for researchers, medical practitioners, and patients. This uncertainty arises from the lack of clear and specific guidelines regarding the boundaries and procedures that must be followed, which can directly affect the implementation of research and clinical practice. For researchers, legal gaps can hinder the progress of stem cell research and technology development. Without clear regulations, researchers may have difficulty in determining the ethical and legal boundaries that must be followed, and in submitting research proposals that comply with applicable standards. It can result in delays or even termination of research projects, as well as hindering scientific progress that is important for the development of new therapies.

Medical practitioners, on the other hand, face challenges in providing appropriate and safe care if stem cell regulations are unclear. The lack of comprehensive guidelines can lead to uncertainty in clinical practice, including decisions about which therapies to provide to patients and how to manage the associated risks. In addition, the lack of clear regulations can lead to differences in the application of standards across healthcare facilities, which can ultimately affect the quality and consistency of patients's treatment. For patients, the legal vacuum poses significant risks related to the safety and effectiveness of stem cell therapy. Without adequate regulation, patients may not be sufficiently informed about the potential benefits and risks of the received therapy. In addition, legal uncertainty can lead to irresponsible medical practices or even fraud, where patients may become victims of untested or unsafe therapies.

Ambiguity in regulations related to stem cell technology can significantly impact research and development in this field. When regulations governing the use and research of stem cells are unclear or incomplete, researchers often face confusion regarding the boundaries they must adhere to, the procedures they must follow, and the standards they must meet. This uncertainty may discourage researchers from continuing or initiating new research projects, hindering innovation and scientific progress. One of the primary impacts of regulatory ambiguity is the delay in the research application and approval

process. Researchers may need to spend valuable time navigating legal uncertainties and seeking clarification on applicable regulations, which can slow down the pace of research and increase costs. The complex and poorly defined processes for obtaining permits and conducting research may cause institutions and biotech companies to hesitate before investing in stem cell projects, ultimately stifling the development of innovations.

Furthermore, regulatory ambiguity can lead to inequality in research practices. Without clear guidelines, researchers in different locations may apply varying standards, resulting in research outcomes that are inconsistent or difficult to compare. Discrepancies in standards and procedures can also hinder collaboration between institutions, crucial for scientific advancement and research findings interpretation into clinical applications. Ambiguity in regulations can also create uncertainty regarding the ethics and rights associated with stem cell research. Researchers may be unsure how to address ethical issues, such as the use of embryonic stem cells, which can influence their decisions in study design and execution. Its not only affects research quality but also raises concerns about compliance with essential ethical principles.

Irregularities in the use of stem cell technology can pose serious risks to patients and society, particularly if regulations are not stringent enough or are inconsistently enforced. One of the primary risks is the potential harm to patient safety. Without clear and strict standards, there is a possibility of using stem cells that are unsafe or have not been proven effective, leading to undesirable side effects, medical complications, or even long-term health damage. Without adequate oversight, patients may receive untested or medically inappropriate therapies, which could jeopardize their health.

Further than safety issues, the ambiguity in stem cell regulation can also result in ethical risks. A major concern is the use of embryonic stem cells, which involves the destruction of human embryos. Without clear ethical guidelines, this practice could raise moral dilemmas and controversies regarding the rights of embryos and their status as potential life. Patients and the public may have concerns about the ethical implications of the therapies they receive, and this uncertainty could influence their willingness to participate in research or use stem cell therapies.

Ethical issues also relate to the transparency of information provided to patients. Without adequate regulation, patients may not be adequately informed about the risks, benefits, and alternatives of stem cell therapy. This can lead to uninformed decisions and may expose patients to unnecessary risks. In addition, the lack of strict regulation can open the door to unethical medical practices or even fraud, where patients may fall victim to therapies that have no sound scientific basis.

The rapid and dynamic development of stem cell technology requires that existing regulations be updated to accommodate new scientific advances and clinical applications. Current regulations may be inadequate to address the latest innovations in stem cell technology, which can create significant legal and ethical gaps. Stem cell technology has advanced rapidly in recent years, with discoveries and increasingly sophisticated applications in disease therapy and medical research. Out-of-date regulations can act as a barrier to safe and effective research and development, and may potentially overlook new risks and challenges that arise as the technology advances.

Regulatory updates are needed to ensure that regulations can cover the many aspects of new stem cell technology, including embryonic stem cells, genetic modification, and complex clinical applications. Existing regulations may be based on outdated knowledge and practices, and therefore unable to regulate new techniques and applications that may have different implications for patient safety, ethics, and therapeutic efficacy. Without

updates, there is a risk that existing regulations will not be able to address new challenges, such as long-term risk management, quality control, and monitoring of stem cell therapy outcomes.

In addition, regulatory updates are important to ensure alignment with international standards. As stem cell research and applications become increasingly global, national regulations must be aligned with international guidelines and standards to facilitate global collaboration, maintain quality, and protect patients. Regulations that are outdated or inconsistent with international practices can limit research opportunities, hinder scientific progress, and put patients at unnecessary risk. Regulatory updates are also needed to respond to rapidly evolving technologies and adapt to new ways stem cells may be used. For example, new technologies in gene editing and cell engineering may introduce risks and benefits that are not yet fully understood. Updated regulations must accommodate and effectively regulate these technologies, ensuring that research and applications are conducted in a safe, ethical, and evidence-based manner.

Legal reformulation related to stem cell technology must be carried out with a holistic approach, considering various important aspects such as ethics, safety, and effectiveness. To ensure that new regulations can accommodate the development of stem cell technology effectively, here are some recommendations for legal reformulation that need to be considered:

1. Establishing Strict Safety Standards

The new regulation should establish clear and strict safety standards for stem cell technology usage. It includes establishing mandatory testing procedures before stem cell therapy can be applied to patients, as well as establishing standards for the quality and safety of the stem cells used. Testing protocols should include long-term risk evaluations, as well as monitoring mechanisms to detect and manage side effects that may arise after therapy. Regulations should also regulate how stem cells are handled and stored to reduce the risk of contamination or damage that could affect the outcome of therapy.

2. Integrating Ethical Aspects into Regulations

Regulations should address and integrate ethical considerations related to the use of stem cells, especially embryonic stem cells. Ethical guidelines should be clear about the limitations of the use of embryonic stem cells, including the consent required and the treatment of embryos. It is also important to regulate how ethical information is conveyed to patients, including transparency about the potential benefits and risks of stem cell therapy. The establishment of an independent ethics committee with the authority to assess research proposals and clinical applications can also ensure that all ethical aspects are properly accommodated.

3. Enhanced Transparency and Information

New regulations should promote transparency in stem cell research and practice by requiring comprehensive reporting of methods, results, and risks. Information about stem cell therapies should be provided to patients, including scientific evidence supporting the effectiveness of the therapy and potential risks. In addition, regulations should address how research and development results are announced to ensure that information made available to the public is accurate and not misleading.

4. Alignment with International Standards

Legal reform should consider alignment with international standards and guidelines on stem cell technology. This is important to ensure that national regulations are not only relevant to global practice but also support international

collaboration in research and therapy. Adopting international principles and best practices can help reduce the gap between national and international regulations, and facilitate the integration of stem cell technology on a global scale.

5. Establishment of Oversight and Enforcement Mechanisms

New regulations should include effective oversight mechanisms to ensure compliance with safety, ethics, and efficacy standards. Establishment of an independent regulatory body responsible for monitoring stem cell research and clinical applications can assist in regulatory enforcement and resolution of emerging issues. In addition, mechanisms for reporting violations and complaints must be provided, so that any practices that do not comply with regulations can be followed up appropriately.

CONCLUSION

The legal void in the regulation of stem cell technology poses a variety of significant challenges, ranging from uncertainty for researchers, medical practitioners, and patients, to security and ethical risks that can harm the health and rights of individuals. The absence of clear and comprehensive guidelines can impede research progress, result in unsafe practices, and create unresolved ethical dilemmas. To address this problem, in-depth and detailed legal reformulation is necessary. Reformulation should include updating security standards, integrating strong ethical aspects, increasing information transparency, conforming to international standards, and establishing effective monitoring mechanisms. By carrying out comprehensive legal reformulation, regulations can provide the necessary legal certainty, support safe and ethical innovation, and better protect the interests and welfare of the community, along with the rapid and complex development of stem cell technology.

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