

# Stem Cell Cells in Health Services in Indonesia

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## Article Info

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## Abstract

Health law in Indonesia has undergone significant transformation in facing the dynamics of community needs and global challenges. As a country committed to improving the health of its citizens, Indonesia has implemented various regulations covering aspects of health services, management of medical personnel, medical education, and disease control. However, the sectoral approach in previous regulations often resulted in overlapping authorities, different legal interpretations, and challenges in policy implementation. To address the need for legal harmonization in the health sector, the government has enacted Law of the Republic of Indonesia Number 17 of 2023 concerning Health (hereinafter referred to as the Health Law) as a new foundation in the development of national health law. This study discusses how the implementation of Law Number 17 of 2023 concerning Health can strengthen the harmonization of the health legal system in Indonesia in overcoming overlapping regulations and improving the quality of national health services. This study was conducted using a normative legal approach method. This research has a conclusion that although the 2023 Health Law has great potential in strengthening the harmonization of the health legal system and improving the quality of services, its implementation is not free from challenges. Some of the main challenges include: Infrastructure and Human Resource Limitations: Many health facilities, especially in remote areas, still face limitations in infrastructure and adequate medical personnel to support the implementation of digital technology and health information systems; Resistance to Change: Some health workers and health institutions may show resistance to the changes stipulated in the 2023 Health Law, especially if they are not given a *Stem cells stem cells* are one of the breakthroughs in health science that has great potential in treating various diseases. Along with the development of technology, the use of stem cells also invites attention in the legal aspect. In this paper, we will discuss the legal analysis of stem cells based on legal theory, health law, Law of the Republic of Indonesia Number 17 of 2023 concerning Health, and the Regulation of the Minister of Health of the Republic of Indonesia. Stem cells are currently a trend in health services, so they have received attention from practitioners and the government, as was done by the Indonesian Food and Drug Supervisory Agency (BPOM) which inaugurated the Advanced Stem Cell Building. Cell Therapy-Production Laboratory (ACT- PLab) Phase I on Monday (11/12/2023) Located in the Kramat area, Central Jakarta, ACT- PLab is the first laboratory used for the processing of stem cells, cells, and their derivatives managed by PT Prodia. StemCell Indonesia (ProSTEM). Stem cell services provide a philosophical basis for understanding the norms and principles governing the use of stem cells. This study discusses the Legal Status of Stem Cells in Health Services; How is Legal Protection for Patients in Stem Cell Health Services; and How is Criminal Liability for Negligence in Stem Cell Health Services. This study was conducted using a normative legal approach method. This study concludes that the legal study of legal status, legal protection, and criminal liability in stem cell-based health services emphasizes the importance of comprehensive regulation and effective law enforcement to create a safe, ethical, and fair service system. Law Number 17 of 2023 concerning Health, together with the Regulation of the Minister of Health Number 833/MENKES/PER/IX/2009, provides a strong legal

basis for regulating the use of stem cell therapy, including standard service requirements, protection of patient rights through informed consent, consent, and sanctions for violations. Through the application of the theory of the rule of law, the state not only protects patient rights, but also ensures that technological innovations such as stem cell therapy can develop without ignoring ethical and safety principles. Enforcement of administrative, criminal, and ethical sanctions provides a deterrent effect for violators, while strict education and supervision strengthen public trust in health services. With a comprehensive approach, stem cell therapy can be a medical solution that provides great benefits to society, while upholding justice, legal certainty, and social responsibility. The author's suggestion in this study is to support the development and implementation of safe, ethical, and effective stem cell therapy, there are several steps that can be taken. First, the government needs to increase efforts to socialize and educate the public about the benefits, risks, and regulations related to stem cell therapy. This aims to improve public health literacy and prevent misunderstandings or fraud that can harm patients. Second, supervision of health facilities that provide stem cell therapy services needs to be strengthened. Periodic inspections, quality audits, and monitoring of medical protocols must be carried out consistently by the Ministry of Health to ensure compliance with regulations. In addition, training for medical personnel related to stem cell therapy needs to be improved, both in terms of technical aspects and legal and ethical aspects, so that they are able to provide professional and responsible services. Third, the government can consider subsidies or health insurance schemes to ensure equal access to stem cell therapy, especially for the less fortunate. Thus, the benefits of this innovation can be felt by all levels of society without discrimination. Finally, collaboration between the government, academics, and the private sector in research and development of stem cell therapy needs to be expanded. This collaboration can accelerate innovation, ensure the use of safe technology, and support the implementation of best practices according to international standards. With a holistic approach, stem cell therapy can make a significant contribution to improving the quality of health services in Indonesia. Dequate training or socialization; Inter-agency Coordination: Harmonization of regulations requires close coordination between various government agencies, such as the Ministry of Health, BPJS Kesehatan, and local governments. Lack of coordination can hamper the implementation of regulations. The author's suggestion in this study is that this law can create the harmonization needed to improve efficiency, transparency, and quality of health services. However, the success of implementing this law depends on the ability of the government, health institutions, and the community to overcome existing challenges. With the right implementation strategy, the 2023 Health Law can be a solid foundation for a more equitable and quality national health system.

**Keyword:**

Legal Protection, Use of Stem Cells, Health Services

## 1. INTRODUCTION

Stem cells stem cells are one of the breakthroughs in health science that has great potential in treating various diseases. Along with the development of technology, the use of stem cells also invites attention in the legal aspect. In this paper, we will discuss the legal analysis of stem cells based on legal theory, health law, Law of the Republic of Indonesia Number 17 of 2023 concerning Health, and the Regulation of the Minister of Health of the Republic of Indonesia. Stem cells are currently a trend in health services, so they have received attention from practitioners and the government, as was done by the Indonesian Food and Drug Supervisory Agency (BPOM) which inaugurated the Advanced Stem Cell Building. Cell Therapy-

Production Laboratory (ACT- PLab ) Phase I on Monday (11/12/2023) Located in the Kramat area, Central Jakarta, ACT- PLab is the first laboratory used for the processing of stem cells, cells, and their derivatives managed by PT Prodia. StemCell Indonesia (ProSTEM). Stem cell stewardship provides a philosophical basis for understanding the norms and principles governing the use of stem cells. In this context, it is therefore essential to first analyze:

a. Ethical Aspects

The use of stem cells is often related to ethical issues, especially those related to the source of the stem cells themselves, such as from embryos or adult tissue.

b. Justice and Access

The theory of justice in law emphasizes the importance of fair access to stem cell-based therapies for all levels of society.

c. Health Law and Stem Cell Regulation

Health law in Indonesia regulates various aspects related to public health. In the context of stem cells, there are several regulations that need to be considered, namely Health Law 17 of 2023. This law regulates health services, including innovation in therapy. In certain articles, there are provisions that regulate the use of stem cells, which must meet certain standards to ensure safety and effectiveness. The next Minister of Health Regulation, namely the Minister of Health Regulation relating to stem cells, also emphasizes aspects of safety and ethics. This regulation regulates the procedures for taking, storing, and using stem cells in medical practice.

Stem cells are undifferentiated cells, meaning they can turn into specific cells such as heart cells, blood cells, and bone cells. Stem cells come from two main sources, adult tissue and embryos. Researchers have also developed various techniques to program stem cells to turn into other cells. In general, *stem cell sources can be divided into two* , namely adult stem cells and embryonic stem cells.

### *Adult Stem Cells*

Adults have stem cells in their bodies. These stem cells can be used for various body needs. Adult stem cells are in a non-specific state, so they have not turned into special cells. However, adult stem cells have more specialized properties than embryonic stem cells. Adult stem cells are in this state until they turn into special cells such as intestines, bone marrow, and other cells. Stem cells function to help the body *regenerate* itself. For example, in the digestive tract and bone marrow, stem cells will divide regularly to renew themselves. Stem cells have been found in various body tissues such as the brain, bone marrow, blood vessels, muscles, skin, and liver .

### *Embryonic Stem Cells*

Since the first stage of labor, after the sperm fertilizes the ovum, the embryo will form. After 3-5 days after the sperm fertilizes the ovum, the embryo will form blastocyst cells. Blastocyst cells contain stem cells and will then implant in the uterus. Embryonic stem cells come from blastocysts that are 4-5 days old. When this type of stem cell is taken, usually these cells come from donors who are undergoing *in vitro fertilization*. *In vitro fertilization* is fertilization that is carried out outside the uterus to facilitate pregnancy in couples who have difficulty having children. When there is an excess of embryos in this procedure, researchers will take the excess to be used as embryonic stem cells. This type of stem cell can then be given special treatment so that it can change into various body cells such as blood cells, skin cells, and various types of cells needed by the body.

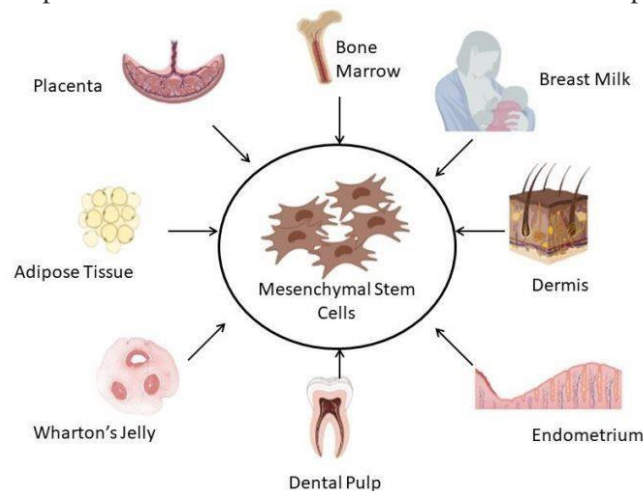
### *Adult Cells That Have Properties Like Embryonic Stem Cells*

Researchers have successfully transformed adult stem cells into stem cells that have properties similar to embryonic stem cells. This technique could cause this new type of stem cell to prevent rejection by the patient's immune system. However, the side effects of this type of stem cell are still questionable. Researchers have been able to take connective tissue from the body and turn it into functional heart cells. Animal studies suggest that much more research is needed to make this type of cell transplantation possible.

### *Perinatal Stem Cells*

Perinatal stem cells are found in amniotic fluid and are found in umbilical cord blood. These stem cells have the ability to turn into specific cells. Amniotic fluid fills the sac that surrounds the fetus. Researchers

have found that samples of stem cells in this amniotic fluid can be turned into stem cells. Stem cells are a therapy that can be used for a variety of diseases. These cells still need further research to assess their effectiveness and safety. However, early studies have shown that these cells have extraordinary potential to be the answer to a variety of problems in medical science. Here are some examples of stem cells:



Based on this, the author is interested in discussing this problem, which the author then gave the title: "Review of Legal Protection Regulations for the Use of Stem Cells ( *Stem Cells*)". *Cell* ) In Health Services in Indonesia ”.

#### *Formulation of The Problem*

1. What is the Legal Status of Stem Cells in Health Services?
2. How is Legal Protection for Patients in Stem Cell Health Services?
3. What is Criminal Liability for Negligence in Stem Cell Health Services?

#### *Research Purposes*

Every research has a goal that must be achieved, so this research aims to be in accordance with the formulation of the problem above, so the objectives of this research are:

1. To find out the legal status of stem cells in health services
2. To find out and analyze Legal Protection for Patients in Stem Cell Health Services
3. Criminal Liability for Negligence in Stem Cell Health Services

#### *Benefits of Research*

##### 1. Academic Benefits

Academic benefits are a requirement in completing educational assignments at the Islamic University of Bandung and the results of this study can add to the literature of Doctoral Law Study Program Students, Faculty of Law, Islamic University of Bandung.

##### 2. Theoretical Benefits

The theoretical benefit is to provide a contribution of thought or as a basis and reference for subsequent research and improving the quality of knowledge.

## **2. RESEARCH METHODOLOGY**

### 1. Writing Nature

This writing uses descriptive research. Descriptive writing aims to accurately describe the characteristics of an individual, condition, symptom or certain group or to determine the spread of a symptom or to determine whether or not there is a relationship between one symptom and another in society.

## 2. Writing Type

This type of writing uses a normative legal approach or this library is a writing that examines document studies, namely using various secondary data such as laws and regulations, court decisions, legal theories, and can be in the form of opinions of scholars.

## 3. Method of collecting data

The data collection technique in this writing is by using the Library Writing method . *Research* ) Library technique is "Bibliography writing carried out by reading, reviewing and recording various literature or reading materials that are in accordance with the topic, then filtered and poured into a theoretical framework of thought".

## 4. Data Types

The author in this study uses Secondary Data , namely "data obtained or collected by people conducting research from existing sources". Secondary data is in the form of books, journals, encyclopedias, magazines, papers, articles and others that are relevant to the problem regarding the author's research title.

## 5. Data analysis

In the process of analyzing data in this study, qualitative analysis was used , which is a method of analyzing data sourced from legal materials based on concepts, theories, laws and regulations, and expert opinions and the research's own views.

### 3. RESULT AND DISCUSSION

#### *Legal Position of Stem Cells in Health Services*

The use of stem cells in health services in Indonesia has become a very relevant issue in the era of rapid development of medical technology. The legal status of stem cells in health services is based on regulations contained in Law Number 17 of 2023 concerning Health (hereinafter referred to as the Health Law). This law establishes various principles and rules governing the use of stem cells to ensure safety, effectiveness, and ethics in medical practice. The Health Law defines health broadly as a person's healthy state physically, mentally, and socially, which allows for productive life. The use of health technology, including stem cells, is regulated as part of curative, rehabilitative, and regenerative health efforts. Stem cells themselves are a technology used to replace body tissue or cells damaged by disease or injury. In Article 22 of the Health Law, stem cells are recognized as a form of cell-based therapy that is integrated into health efforts that include promotive, preventive, curative and rehabilitative efforts. Article 4 of the Health Law guarantees the right of every individual to obtain safe, quality, and standard health services. In the context of stem cell therapy, the protection of patient rights is a very important aspect. Patients have the right to receive complete information about the risks, benefits, and procedures of therapy before giving informed consent . consent ). This provision also refers to Article 23 of the Health Law which states that all health services must be carried out responsibly, safely, with quality, evenly and non-discriminatory. One of the important elements in the legal status of stem cells is informed consent. Patients must be given clear information about the potential benefits and risks of this therapy. This regulation refers to the principle of protection and safety in Article 2 letter g and respect for individual rights in Article 4 paragraph (1) letter h of the Health Law.

Article 24 of the Health Law states that the implementation of health efforts, including the use of stem cells, must comply with health service standards stipulated in government regulations. In this case, the Regulation of the Minister of Health Number 833/MENKES/PER/IX/2009 provides technical guidelines on the implementation of stem cell therapy, including aspects of its collection, processing, storage, and use. This regulation aims to ensure that stem cell practices are carried out according to applicable standards and minimize risks to patients. To ensure compliance with regulations, the Health Law also stipulates administrative, criminal, and ethical sanctions for violations related to the use of stem cells. Article 10 of the Health Law states that the central and regional governments are responsible for supervising health resources, including cell-based therapy. Violations of safety and ethical standards can be subject to sanctions in the form of revocation of practice permits, administrative fines, or even criminal sanctions if there is an element of negligence that endangers patients. In addition to the legal aspect, the use of stem cells is also regulated based on ethical and moral values as stated in Article 2 letter k. Stem cell-based research and therapy must respect human dignity and consider its impact on society. This is also regulated in the Regulation of the Minister of Health which requires ethical testing before research or therapy is carried out. Article 9 of the Health Law emphasizes the government's responsibility to ensure equal access to health services. In the



context of stem cell therapy, this means ensuring that this therapy is not only available to certain groups, but can be accessed by all levels of society at an affordable cost.

Article 7 of the Health Law stipulates that research and assessment of health technology must be carried out in accordance with the provisions of laws and regulations. The government also encourages innovation in the field of stem cell therapy to present new, more effective and safe medical solutions. This regulation opens up opportunities for collaboration between the government, academic institutions, and the private sector in the development of cell-based therapies. Article 19 of the Health Law states that the government is responsible for implementing health efforts, including supervision of stem cell-based therapies. The Ministry of Health has the authority to conduct inspections, audit the quality of services, and take action against violations of regulations. This strict supervision system aims to maintain public trust in the safety and effectiveness of stem cell therapy. Article 38 of the Health Law supports the development of national centers of excellence that meet international standards. Cooperation with other countries can accelerate the adoption of new technologies and the implementation of best practices. practices in stem cell therapy in Indonesia. The legal status of stem cells in health services in Indonesia is a reflection of the state's commitment to utilizing health technology responsibly. With strict regulations, protection of patient rights, and good law enforcement, stem cell therapy can be developed ethically and provide maximum benefits to the community. Effective implementation requires collaboration between the government, medical personnel, and the community to ensure that this therapy is not only safe and effective, but also fairly accessible to all groups.

#### *Legal Protection for Patients in Health Services Cell Cause*

Legal protection for patients in health services, including stem cell therapy, is a very important aspect in maintaining patient rights and safety. As a promising form of medical innovation, stem cell therapy offers the potential to cure various diseases that were previously difficult to treat. However, this technology also carries risks, both medically and legally, which must be anticipated through adequate regulation and legal protection. Patient rights are one of the main pillars of health services in Indonesia. The Health Law strictly regulates various patient rights, including in the context of stem cell therapy. Patients have the right to receive complete information, safe services, and consent for medical actions to be carried out. Article 4 of the Health Law states that everyone has the right to safe, quality, and standardized health services. This means that stem cell therapy must be carried out with established procedures, using competent medical personnel, and supported by adequate health facilities. This right is the basis for legal protection given to patients so that they do not become victims of negligence or malpractice.

#### *Article 4*

##### *(1) Everyone has the right:*

- a. *living healthy physically, mentally and socially*
- b. *get information and education about balanced and responsible health;*
- c. *obtain safe, quality and affordable health services in order to achieve the highest level of health;*
- d. *get health care according to standards*

##### *Health services;*

- a. *gain access to Health Resources;*
- b. *determine the Health Services needed for oneself independently and responsibly;*
- c. *get a healthy environment for achieving a degree*

##### *Health;*

- a. *accept or reject some or all of the assistance measures to be given to him/her after receiving and understanding complete information regarding such measures;*
- b. *obtain confidentiality of personal health data and information;*
- c. *obtain information about his/her health data, including actions and treatments that he/she has received or will receive from medical personnel and/or health workers; and*
- d. *get protection from health risks*

One form of legal protection for patients is through informed consent . consent . Informed Consent is a process in which patients are given clear and complete information about a medical procedure, including benefits, risks, alternative therapies, and possible side effects. Article 23 of the Health Law states that every

medical action must be carried out based on the patient's consent after the patient understands the information provided. In the context of stem cell therapy, the information that must be provided includes:

1. Origin of the stem cells to be used (embryonic, adult, or perinatal ).
2. Risks of the procedure, such as possible allergic reactions or failure of therapy.
3. Benefits that can be obtained from therapy, such as tissue regeneration or treatment of certain diseases.
4. Alternative therapy options available.

Without any *information consent* , medical actions can be considered as violations of medical law and ethics, which have the potential to give rise to lawsuits from patients. Legal protection for patients also lies in the service standards regulated in laws and regulations. Article 24 of the Health Law states that all health services must be carried out in accordance with the standards set by the government. In this case, the Regulation of the Minister of Health. Health Regulation Number 833/MENKES/PER/IX/2009 concerning the Implementation of Stem Cell Services provides technical guidelines that must be followed by health facilities and medical personnel. Service standards include:

1. Stem cell collection and processing procedures: Stem cell collection from donors must be carried out according to established protocols, using safe technology, and obtaining donor consent.
2. Qualifications of medical personnel: Stem cell services may only be carried out by medical personnel who have special expertise and have received adequate training;
3. Supervision of health facilities: Facilities providing stem cell therapy services must have an operational permit and be regularly supervised by the Ministry of Health.

With this standard, the risk to patients can be minimized, and any violation of the standard can be subject to administrative or criminal sanctions. In health services, protection of the confidentiality of patient information is essential. Article 55 of the Health Law states that every medical personnel and health facility is required to maintain the confidentiality of patient data. In stem cell therapy, data related to donors and recipients of cells must be protected from misuse, such as for commercial purposes without consent.

#### Article 55

*Everyone has the right:*

- a. *live a healthy, safe reproductive and sexual life, free from discrimination, coercion and/or violence, while respecting noble values that do not degrade human dignity in accordance with religious norms;*
- b. *obtain information, education and counseling regarding reproductive health that is correct and accountable; and*
- c. *receive health services and recovery due to criminal acts of sexual violence*

Violation of information confidentiality can result in legal sanctions, either in the form of fines or criminal penalties, as regulated in Article 325 of the Health Law. This protection is important to maintain patient trust in the health care system. Negligence or malpractice in stem cell therapy services can have serious consequences for patients, such as health complications or financial losses. Therefore, the Health Law regulates the accountability mechanism for medical personnel and health facilities that are proven to have committed negligence. Article 320 of the Health Law states that medical personnel who commit negligence that causes serious harm to patients can be subject to criminal sanctions, such as imprisonment for up to five years or a maximum fine of IDR 5 billion. In addition, patients also have the right to claim compensation through civil channels. Effective supervision is an essential element in protecting patients from risks in stem cell therapy. The Ministry of Health is responsible for conducting regular inspections of health facilities that provide these services. Inspections include checking medical protocols, qualifications of health workers, and compliance with service standards. In addition, supervision also includes managing side effects or complications that may occur. Article 29 of the Health Law states that health facilities are required to provide a mechanism to handle patient complaints, including compensation for patients who suffer losses due to negligence.

#### Article 29

- (1) *The community can participate in the development of primary health care facilities and advanced health care facilities.*
- (2) *The development of primary health care facilities and advanced health care facilities as referred to in*

*paragraph (1) includes the provision of human resources, facilities, infrastructure and medical equipment*

- (3) The development of primary health care facilities and advanced health care facilities as referred to in paragraph (1) must take into account the need for health services in remote, border and island areas, including the need for educational facilities.*
- (4) The Central Government and/or Regional Government can assist in providing human resources for the development of primary health care facilities and advanced health care facilities in the regions as referred to in paragraph (3).*

Education for patients and the wider community is also an important form of legal protection. Many patients do not understand what stem cell therapy is, how the procedure works, and its benefits and risks. This can lead to misunderstandings or unrealistic expectations. The government, through the Ministry of Health, has a responsibility to provide accurate and easy-to-understand information to the public. This education program aims to improve public health literacy and prevent fraud or abuse in stem cell therapy. Legal protection for patients also includes aspects of justice in access to stem cell therapy. Article 9 of the Health Law emphasizes the importance of equal access to health services throughout Indonesia. This means that patients from all walks of life, including those who are less fortunate, must have the same opportunity to receive stem cell-based therapy. To support this, the government needs to provide subsidies or health insurance programs that cover stem cell therapy. Thus, the benefits of this medical innovation can be felt by all levels of society. Healthcare facilities that provide stem cell therapy services have significant legal responsibilities to protect patients. These responsibilities include:

- a. Ensure that all procedures are carried out in accordance with applicable standards.
- b. Provide clear and transparent information to patients
- c. Handle complaints or complications quickly and professionally

If health facilities fail to fulfill these responsibilities, they may be subject to administrative sanctions, such as revocation of operating permits, or even criminal charges if they are found to have committed serious violations. Legal protection for patients in stem cell health services is a complex but very important effort to ensure the safety, rights, and welfare of patients. Through clear regulations, strict service standards, and effective supervision, the government and medical personnel can create a safe and trusted health care environment. By continuing to improve education, fair access, and strict law enforcement, it is hoped that stem cell therapy can develop into a medical solution that provides great benefits to the Indonesian people without sacrificing ethical and legal aspects.

#### *Criminal Liability for Negligence in Service Stem Cell Health*

Negligence in health services, including stem cell therapy, has serious consequences that can harm patients physically, mentally, and financially. Therefore, criminal liability is an important aspect in ensuring that health workers, health facilities, and related parties act in accordance with applicable standards and regulations. Law Number 17 of 2023 concerning Health provides a clear legal basis for regulating criminal liability for negligence in this service. Negligence in health services can be defined as the failure of health workers or health facilities to meet standards of professionalism, care, and legal obligations that result in harm to patients. In the context of stem cell therapy, negligence could include:

- a. Errors in stem cell collection or processing
- b. Lack of information consent before medical treatment
- c. Violation of safety standards in therapeutic procedures
- d. Inadequate management of side effects.

Such negligence can give rise to criminal liability if proven to cause significant harm to the patient. The Health Law and the Criminal Code (KUHP) are the main basis for determining criminal liability for negligence in health services. Some relevant articles include:

1. Article 320 of the Health Law: Regulates that health workers who commit negligence resulting in serious harm to patients can be subject to criminal sanctions in the form of imprisonment for up to five years or a maximum fine of IDR 5 billion
2. Article 325 of the Health Law: Affirms that health facilities that are proven to have violated service standards and caused harm to patients can also be subject to criminal liability.



In the Criminal Code, provisions on negligence are regulated in Article 359, which states that anyone who, due to negligence, causes the death of a person can be subject to a maximum prison sentence of five years or imprisonment. Health workers and health facilities have a legal obligation to ensure that all medical procedures, including stem cell therapy, are carried out in accordance with applicable standards. These obligations include:

1. Provide complete and accurate information to patients before medical procedures are performed.
2. Ensuring that stem cell collection, processing and application procedures are carried out safely.
3. Anticipate and manage complications or side effects that may arise during or after therapy.

If this obligation is not fulfilled and there is evidence of negligence, the party concerned can be held criminally responsible. To prove a criminal act in a case of negligence, several elements must be met, namely:

1. Existence of acts or omissions: Medical actions that are not in accordance with standards or negligence in carrying out duties
2. There are adverse effects on the patient: For example, serious complications, tissue damage, or even death
3. Causal relationship: There must be evidence that the act or omission directly caused harm to the patient
4. There must be an element of error: The negligence must be categorized as a violation of professional standards or legal obligations.

The Health Law and the Criminal Code stipulate various types of criminal sanctions that can be imposed for negligence in health services. These types of sanctions include:

1. Imprisonment: Imposed on negligence that causes serious harm to patients, including death or permanent disability
2. Criminal Fines: Health facilities or medical personnel who violate service standards may be subject to fines according to the level of violation
3. Additional Sanctions: For example, revocation of a practice permit or a ban on practicing for a certain period of time.

This sanction aims to provide a deterrent effect while protecting patient rights and safety. Law enforcement against negligence in stem cell health services involves several stages, namely:

1. Complaints by Patients or Family: Cases usually begin with a complaint by a patient or family who feels aggrieved
2. Investigation by Health Authorities: The Ministry of Health or related agencies will conduct an initial investigation to determine whether there has been a violation of service standards
3. Legal Process: If evidence of a violation is found, the case will proceed to the criminal legal process, where the public prosecutor will file charges based on the available evidence.
4. Court Decision: The judge will determine whether the perpetrator is guilty and impose sanctions in accordance with the provisions of the law.

Examples of Negligence Cases in Stem Cell Therapy include several cases of negligence that can be used as examples, including:

1. Case of Stem Cell Harvesting Without Consent: Stem cell harvesting from donors without informed consent is considered a serious violation of patient rights
2. Errors in Stem Cell Processing: For example, using stem cells that have been contaminated or do not meet safety standards
3. Inadequate Management of Side Effects: Negligence in managing complications that arise after stem cell therapy can be considered malpractice .

To prevent negligence, health workers and health facilities must receive adequate training on the use of stem cell therapy. The government also needs to conduct educational programs to improve health workers' understanding of their legal responsibilities. Strict supervision by the Ministry of Health and related institutions is essential to prevent negligence in stem cell therapy services. Supervision includes regular inspections, quality audits, and monitoring of medical procedures performed. Criminal liability for negligence in stem cell healthcare services is an essential element to ensure patient safety and maintain public trust in the healthcare system. With clear regulations, strict service standards, and effective law enforcement, the risk of negligence can be minimized. The government, healthcare workers, and healthcare facilities have a shared responsibility to create a safe, ethical, and professional service environment, so that

the benefits of stem cell therapy can be maximized by the community. Criminal liability for negligence in stem cell healthcare services is a very important issue in ensuring legal protection for patients while upholding justice in medical practice. Stem cells as one of the innovations in the health sector offer great potential in the treatment of degenerative and regenerative diseases. However, behind the advantages of this technology, the risk of negligence in its implementation remains and requires serious attention. Negligence, both technical and ethical, can cause significant harm to patients, ranging from medical complications to violations of their basic rights.

From a legal perspective, negligence in health services including stem cell therapy is categorized as a criminal act if it meets certain elements. Negligence can occur when medical personnel or health facilities fail to carry out their obligations according to applicable operational standards. For example, errors in stem cell processing that cause serious infections or the use of stem cells without informed consent from the patient. In this case, the causal relationship between the perpetrator's actions or omissions and the patient's losses must be legally proven. This is in line with the provisions of Law Number 17 of 2023 concerning Health, which provides a legal framework regarding criminal liability for medical personnel and health facilities. The Health Law explicitly regulates legal protection for patients and sets high standards in the implementation of health services. Article 320 of this law stipulates that negligence that causes serious harm to patients can be subject to criminal sanctions in the form of imprisonment for up to five years or a maximum fine of IDR 5 billion. This provision confirms that the state takes seriously medical practices that do not comply with the rules, especially in the use of medical technology such as stem cells. In addition, Article 325 of the Health Law expands the scope of legal responsibility to include health facilities that are proven to have violated regulations. This sanction is designed to create a deterrent effect while maintaining public trust in the health care system. Negligence in stem cell services is often related to procedural violations such as unauthorized stem cell collection or non-compliance with applicable medical protocols. Minister of Health Regulation Number 833/MENKES/PER/IX/2009 concerning the Implementation of Stem Cell Services provides detailed guidelines regarding the implementation of this therapy. This regulation emphasizes the importance of informed consent as a fundamental element in every medical action. Failure to comply with this regulation not only endangers the patient, but also violates applicable ethical and legal principles. In the context of a state of law, such actions cannot be tolerated and must be dealt with firmly.

Fair and effective law enforcement is key in handling cases of negligence in stem cell-based health services. In this case, the theory of the rule of law serves as a foundation to ensure that all legal actions are carried out based on the principles of justice, legal certainty, and benefit. The state is responsible for providing legal protection to the community, including through clear regulations and the application of strict sanctions against violations. Law enforcement in cases of negligence in stem cell services must include a transparent process, from investigation to court decisions. In addition, the theory of criminal responsibility provides a practical approach to determining the responsible party in cases of negligence. In this theory, both individuals such as medical personnel and institutions such as hospitals can be held legally responsible if proven guilty. The legal process in this context aims not only to provide justice for the injured patient, but also to ensure that the perpetrators of negligence understand the consequences of their actions and prevent the recurrence of similar violations. The implementation of criminal liability in stem cell services also has a close correlation with the protection of human rights. The state is obliged to protect patients as the main subjects in health services. This includes the patient's right to clear information, the right to safe services, and the right to be free from exploitative or high-risk medical practices without adequate scientific basis. By strictly enforcing the law, the state demonstrates its commitment to maintaining the dignity and safety of patients in every health service process. However, law enforcement is not enough just by imposing sanctions. Education and training for health workers on stem cell procedures and regulations are also integral parts in preventing negligence. The government through the Ministry of Health needs to strengthen the supervision and inspection system for health facilities that provide stem cell therapy services. Regular inspections, quality audits, and education programs on ethical and legal standards are strategic steps to increase awareness and competence of health workers. In its implementation, legal protection for patients in cases of negligence in stem cell services not only includes aspects of national regulations, but also utilizes universal principles in medical practice. By referring to international standards and best practices, Indonesia can ensure that the use of stem cells is carried out responsibly, safely, and ethically. This approach not only increases public trust in health services, but also encourages the development of sustainable medical innovation.

#### 4. CONCLUSION

The conclusion of the legal study on the legal status, legal protection, and criminal liability in stem cell-based health services emphasizes the importance of comprehensive regulation and effective law enforcement to create a safe, ethical, and fair service system. Law Number 17 of 2023 concerning Health, together with the Regulation of the Minister of Health Number 833/MENKES/PER/IX/2009, provides a strong legal basis in regulating the use of stem cell therapy, including service standard requirements, protection of patient rights through *informed consent*, *consent*, and sanctions for violations. By implementing the theory of the rule of law, the state not only protects the rights of patients, but also ensures that technological innovations such as stem cell therapy can develop without ignoring the principles of ethics and safety. Enforcement of administrative, criminal, and ethical sanctions provides a deterrent effect for violators, while strict education and supervision strengthen public trust in health services. With a comprehensive approach, stem cell therapy can be a medical solution that provides great benefits to society, while upholding justice, legal certainty, and social responsibility.

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