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## STEM CELLS SERVICE LEGALITY POST-APPLICATION OF LAW NUMBER 36 YEAR 2009 ABOUT HEALTH

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### A BSTRACT

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*The development of stem cells services has grown rapidly throughout the world since 2004, as well as in Indonesia. This is because stem cells have unique properties that can differentiate into various cells types, making it promising to repair tissue damaged by various diseases, especially degenerative conditions. The purpose of this study was to obtain an overview of the regulation of stem cells services so that it can be carried out to the public after the enactment of the Health Law Number 36 of 2009 and to obtain an overview of the implementation of the law in stem cells regulation that is not yet comprehensive. The research methodology used is juridical normative, with a statutory approach, a conceptual approach. Also by using a comparative approach with other countries. This study analyzes substantially the regulation of stem cells and/or cells services based on Minister of Health Regulation number 32 of 2018 concerning stem cells and/or cells services and the implementation of laws against violations in their implementation. The regulations that are not yet comprehensive have in the competence of doctors who carry out stem cells services both as standardized therapy and service-based research that has not been certified, as well as the implementation of the law to use laws and regulations that are generally used for cases of non-specific illegal acts that result in prosecution. which is multi-layered. So that it is*

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*necessary to regulate stem cells according to the hierarchy of legislation and need to revise Minister of Health Regulation number 32 of 2018 so that it can be implemented safely and effectively and accommodate the orientation of technology development in the stem cells sector in Indonesia.*

**KEYWORDS**

Stem Cells, Comprehensive Regulation, Legality



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## INTRODUCTION

The development of technology and the rapid flow of globalization can bring up new problems in society. One example of a service in the health sector that requires clearer regulation is a service that uses stem cells. Stem cells are increasing in the community and many are starting to pay more attention to the role of these cells in the health sector.

The limitation of stem cells according to article 1 of the Minister of Health Number 833 of 2009 is a cells in the human body with a special ability to renew or regenerate itself (self regenerate/self renewal) and is able to differentiate into other cells (differentiate) (Decree of the Minister of Health No. 833 of 2009 Concerning Stem Cells in Health Services, n.d.)

Stem cells are unspecialized cells that have the ability or potential to develop into specific types of cells that make up various body tissues. Stem cells are released into damaged organs to repair them. Therefore, stem cells become very important in the process of tissue regeneration. Stem cells are released into damaged organs to repair them. Therefore, stem cells become very important in the process of tissue regeneration ([Evison, 1986](#))

Stem cells have unique properties that make them an alternative to cure chronic, degenerative, and acute diseases by repairing damaged tissues and organs ([Vaugh et al., 2018](#)). Stem cells can also be used to develop pharmaceutical fields through more effective drug testing ([Hatzimichael & Tuthill, 2010a](#)).

In general, stem cells are classified into 3 types, embryonic stem cells, adult stem cells and stem cells resulting from cells induction so that they become pluripotent cells or abbreviated as iPS (induced pluripotent stem cells), in the laboratory ([Eve et al., 2008](#)). iPS stem cells are similar in nature to embryonic stem cells, but are not derived from embryos, so there are no ethical issues.

Stem cells have various uses, including for research purposes that are beneficial for the development of the basic biology of life in various types of cells in the event of disruption, replacement therapy for damaged or lost cells. Stem cells can be replicated to produce new cells, tissues and organs. Tissues or organs formed from stem cells can be transplanted into the body to replace cells that are no longer functioning properly ([Hatzimichael & Tuthill, 2010](#)).

Currently, stem cells can be used to treat various conditions, such as cases of thalassemia, blood cancer, and conditions where blood cells are low due to side effects of treatment. Skin stem cells can be used to produce new skin cells for burn patients. Blindness due to macular degeneration in aging is one example of a condition that can be overcome by the use of stem cells in the future. This blindness is caused by the malfunctioning of the retinal pigment cells, with iPS which can produce new retinal pigment cells, the damaged cells can be replaced so as to avoid blindness.

Stem cells technology needs to be developed as an alternative to disease therapy for the benefit of patients and affordable for the community (Sandra, 2019). Stem cells have great potential in the medical world to be used as a therapy for various degenerative diseases and cancers that are difficult to cure (Huang et al., 2011; Ningrum & Kurniawaty, 2019).

The quality of stem cells services is oriented to the application of a code of ethics and health service standards (Naji et al., 2019). The word legal comes from the word legal (Dutch) which means legal according to the law. Or according to the Indonesian dictionary, legal is defined in accordance with the law or law. From the definitions above, it can be concluded that the legality of stem cells and/or cells services is the use of legal norms that have been ratified by the agency assigned to become the most important source of law and as the basis for carrying out these activities (Veronica Komalawati, 2018).

Law of the Republic of Indonesia Number 36 of 2009 concerning Health is a renewal of Law Number 23 of 1992. This new law aims to provide a legal umbrella for other laws and regulations, legal certainty for the Indonesian people who receive health services and health workers as a health care provider.

The responsibility of the Government as referred to in paragraph (1) is dedicated to public services. This means that the government is required to realize equitable and affordable therapies, including this cells-based therapy.

Although in Indonesia stem cells therapy is still in the development and research stage, the quality of stem cells therapy in Indonesia is comparable to other countries. Of the 379 patients who were treated at RSUD Dr. Soetomo, 30-100 percent improvement in diabetes patients and 60-70 percent knee joint pain. Improvements in stroke patients 50 percent and heart disease 60-80 percent. The same thing was shown in the translation test of therapy participants in RSCM for orthopedic cases and cardiac infarction. Dermama Biotechnology Laboratory in Solo, produces promote stem cells to heal wounds and regenerate injured nerves. Stem cells associations in Indonesia are:

Rejaselindo: is the Association of Indonesian Doctors of Tissue Engineering and Cells Therapy, an association of Indonesian doctors (from various disciplines/specialists) who are engaged in Cells Therapy (including stem cells) and Tissue Engineering. Rejaselindo is under PB IDI.

ASPI: Indonesian Stem Cells Association, is an association that accommodates all elements of society to cooperate with each other so that a wider target in the utilization of stem cells technology through innovations in the fields of science, industry, and social society.

Perbaji: Association of Indonesian Network Banks, is an agency that serves stem cells storage and processing and has received permission from the Ministry of Health based on Minister of Health Regulation no. 48 and 50 in 2012.

Seeing the importance of stem cells services, the Government of Indonesia has made regulations in Indonesia, namely: Health Law Number 36/2009.

Although the article relates to public health in general, it also contains stem cells regulation, such as Articles 64, 66, 70 and 75. Article 64 provides a legal basis for the use of stem cells to cure certain diseases and allows cells transplantation if it is clinically safe for the patient. (Article 66). The most important provision in the Health Law, is Article 70 paragraph 2.

The stem cells as referred to in paragraph (1) may not originate from embryonic stem cells. Further provisions regarding the use of stem cells as referred to in paragraph (1) and paragraph (2) shall be regulated by a Ministerial Regulation. This is in line with Article 75 which prohibits abortion.

Decree of the Minister of Health of the Republic of Indonesia Number HK.02.02/Menkes/541/2016 concerning the Stem Cells Development and Tissue Engineering Committee to provide input and considerations to the Minister in making policies on stem cells development and tissue engineering, including the development and supervision of tissue bank and stem cells banking services in Indonesia.

Clinical applications in translational research must be carried out in educational hospitals with the highest accreditation with a minimum of type B and have human resources with supervisory competence, standardized facilities using products that already have a statutory distribution permit (Baniebrahimi et al., 2019; Chang et al., 2018; Naji et al., 2019).

It is necessary to conduct clinical trials on stem cells therapy because it is part of the development of medical technology. The first phase of clinical trials is to conduct research on healthy humans. It aims to look for side effects from stem cells users. In the second phase, stem cells are tested on people with certain diseases, for which there are no other treatment options. To do this, the patient will also go through a certain series of stages. The third phase, comparing the results of standard treatment with stem cells. The fourth phase or post-marketing phase is stem cells marketing.

The variety of stem cells types is very high, so it is not easy to carry out a series of clinical trials as is done with ordinary drugs. The third phase also cannot be done considering that stem cells treatment is used in the final stages of treatment.

Even though it has been regulated, according to the author, stem cells services still leave various questions, including: Who can and can do it? What products can be used? Where is the place that can do? What facilities are required? How is it set up? Who arranged it? What education is required? Who educates? Who can be educated? From this question, the author will attempt to review based on applicable laws and regulations and clinical practice that has been running.

Based on literature searches and searches to various locations for stem cells and cells services, research on the legal aspects of stem cells services is based on Permenkes no. 32 of 2018 regarding the implementation of stem cells/and or cells services has never been discussed, especially at the postgraduate School of Military Law, as well as other universities.

## **RESEARCH METHOD**

This research is a normative-research, namely research to find legal principles, the rule of law, legal principles, and legal doctrines, in order to answer legal issues regarding the legal aspects of stem cells and/or cells services encountered. For this reason, efforts are made to produce new arguments, theories or concepts as prescriptions in solving problems at hand. This research belongs to the type of normative legal research, namely library law research or legal research based on secondary data. This normative legal research focuses on the object of study on empirical, comparative and historical approaches to the implementation of stem cells and/or cells services from various institutions both at home and abroad.

Normative legal research on assessment (analysis) starts from the articles of positive law containing the concepts of explanation and the nature of the research problem. Next, explore the layers of legal science related to the problem (legal dogmatics, legal theory, and legal philosophy). Sources of data used in writing this thesis is secondary data obtained from the literature to seek, study and collect information, concepts, theories and conceptual thoughts from previous researchers in the form of scientific works and legislation related

to the object of research. The secondary data used are in the form of primary, secondary and tertiary legal materials.

The method used is a qualitative juridical analysis method with induction technique. This is done on secondary data obtained through literature review and tertiary data obtained in accordance with the data collection method above. Induction technique is used to analyze primary data and secondary and tertiary data. The data obtained through library research and field studies were analyzed based on qualitative methods. Explain and describe the relationship between various categories or laws and regulations, then analyzed descriptively qualitatively. Thus, revealing the expected results and conclusions on the problem.

## RESULTS AND DISCUSSION

### 1. Stem Cells Service As A Business Field

So much attention has been paid to stem cells research, and so much potential that can be developed, that some people are starting to enter the stem cells-based healthcare business. Many countries have set up multi-billion dollar development programs, and new companies are emerging. In fact, a number of companies are already marketing commercial treatments using stem cells even though there are no detailed regulations governing them.

Stem cells therapy is very promising, of course everyone wants to be able to live a healthy life and be free from various diseases including degenerative diseases caused by increasing age. With the development of health technology, the elderly population will increase which of course will also increase various degenerative diseases.

To get a quality life back, it is not uncommon for someone to be willing to dig into their pockets even if they have to spend a lot of money. Each stem cells is valued at Rp. 1-1,5 per cells. At first glance it looks cheap, but the number of cells given is quite large in the patient's organs or bodies, so the costs incurred are not small. For one therapy, the cells given can reach tens to hundreds of millions of cells.

Dr Cosphiadi Irawan, SpPD, KHOM, an internal medicine specialist, said that the dose of stem cells given to each patient was different depending on the type of disease. Lupus disease, for example, given stem cells 1-2 million per kilogram of body weight of the patient. If the patient weighs 50 kilograms, the lowest dose is to inject 50 million stem cells, and the maximum dose is 100 million stem cells. So, the cost required is around Rp. 50-150 million in one therapy. Another example for the case of knee osteoarthritis needs 10 million cells per kilogram of body weight. Diabetes 100 million cells, Glaucoma 5 million cells, Spinal Cord 76 million cells.

Stem cells services are very attractive to health business people. In the United States, in 2010, stem cells practitioners made an estimated \$200 million in profits in venture capital and by 2016, that figure had quadrupled. Stem cells technology attracts most of the investment; \$700 million of the \$800 million dedicated to regenerative medicine.

This shows that the stem cells industry, even though it is growing, has enormous profit potential as it relates to life, health and well-being. Stem cells transplantation and the stem cells regenerative industry in general are relatively new technologies and appropriate laws and regulations have not yet been standardized in this field. Laws and regulations surrounding this industry vary by country.

#### 1). Business Idea that has the Potential to Lead to Lawlessness

The lucrative advantages of starting a stem cells business have made many health industry players focus on this business opportunity, including:

##### a. Opening a Stem Cells Bank

Stem cells have become lifesavers, and there is a thriving business revolving around making stem cells available to those who need them for transplant to stay alive.

Stem cells banks collect, test, preserve, and deliver stem cells from donors either for preparation in research, or for future use via cord blood storage.

The governing regulation is the Regulation of the Minister of Health of the Republic of Indonesia Number 48 of 2012 concerning the Operation of Cord Blood Stem Cells Banks. This arrangement is difficult to fulfill regarding establishment permits and operational permits which are full of requirements that can only be carried out by strong investors. This business is indeed capital intensive because it needs to build a bank that is in accordance with regulations. Its development in Indonesia is quite difficult so that what develops are companies from abroad operating in Indonesia:

- 1) Cellsafe : storage in Indonesia and Malaysia
- 2) Cordlife : storage in Indonesia and Singapore
- 3) Cyrocord: storage in Malaysia
- 4) Babybanks: storage in Taiwan
- 5) Stemcord: storage in Singapore

The Prostem, Indonesia company has to wait 3 years to get its license which is only valid for 5 years. Currently, the domestic industry only takes care of licensing for stem cells processing, not as a bank for storing umbilical cord blood cells. The companies are: ProSTEM Laboratory, Regenic, Dermama, Asia Stem Cells and Hayandra.

**b. Open a stem cells therapy clinic**

In the United States alone, there are approximately 160 registered and licensed cells therapy businesses, and the industry generates \$1 billion in annual profits. This shows that the cells therapy industry is really developing. At this point, the industry is still undergoing research and an entrepreneur who is knowledgeable in this area can come up with viable research or products that can help improve the industry. If you are not manufacturing a product, a stem cells therapy clinic can provide a variety of stem cells-related treatments.

Current knowledge is that stem cells can be used to replace neurons damaged by spinal cord injury, stroke, Alzheimer's disease, Parkinson's disease, or other neurological problems; produce insulin that can treat diabetics and heart muscle cells that can repair damage after a heart attack, and others.

In Indonesia, regulations for the establishment of stem cells therapy clinics have not been regulated because there are no stem cells products licensed for distribution, so that the developed services are research-based research which is only recommended in Government Hospitals with permission from the Minister of Health. Research conducted outside of that must have cooperation. In fact, licensed hospitals tend to work independently and do not open collaborations, especially if the research product to be collaborated is a competitor's product. This regulation creates a climate of monopoly among licensed hospitals in the development of service-based research.

Stem cells clinics that are developing, of course, do not have a permit. However, the need for a healthy life for the “desperate” and promising profits has resulted in the development of illegal stem cells clinics.

**c. Opening a stem cells research center**

In many other countries the state of the stem cells industry which is still under research has stimulated great curiosity about medical procedures to utilize human, animal, and even plant stem cells to improve the quality of life. Because research can access funding from the government and other donors, research centers are growing rapidly. In addition, if a product is found, the rights can be owned and can be sold to an established pharmaceutical company. The development of new products, new materials, and new processes related to stem cells can only be done through research. Therefore, many stem

cells research centers have sprung up. It is different in Indonesia, research is constrained by having to cooperate with licensed hospitals, so to be able to produce new stem cells products, we have to stagger. The development of stem cells products that are in high demand, such as for chronic wound healing, anti-aging products, cancer cells therapy, and regenerative medicine, can only be developed in licensed hospitals.

Stem cells services in Indonesia can only be carried out in government hospitals that have received a recommendation from the Minister of Health in accordance with Kepmenkes number 32 of 2014 concerning the Establishment of a Hospital for the Development of Medical Services Research and Education, Tissue Banks and Stem Cells, there are 11 hospitals that are licensed stem cells therapy.

Resource support from the government in the form of preparing human resources and funding for the implementation of stem cells research in Indonesia is still very limited. This is a significant obstacle. Indonesian researchers who have struggled to study abroad cannot apply their competencies because they are not supported by laboratory facilities, funds, and an atmosphere that is not very supportive of the research climate in Indonesia. Meanwhile, in the field of non-human resources, there are still many problems with the price of laboratory equipment (including its maintenance) which is still relatively expensive, and imports of consumables that still seem bureaucratic. Therefore, multicenter collaboration between academia, business, and government or what is often called ABG (Academic, Business and Government) is needed to advance the stem cells industry in Indonesia. If all ABG parties can sit together to continuously discuss how to come up with the best solution for the common interest, we can be ahead of other countries. Multicenter research will save a lot of costs and can accommodate existing resources in various regions to support each other. Of course, this cannot be separated from regulations that must be adjusted by the government.

#### **d. Opening a stem cells tourism center**

The “desperate” population who have strong capital will continue to try to find alternatives to be free from diseases or conditions for which there is no standard therapy. The life expectancy promised by the potential of stem cells has encouraged many health industries to open stem cells tourism clinics, which of course promise huge profits. With the development of the internet and social media, it has paved the way for the development of this clinic.

The journal, published in Science Translational Medicine, calls for harmonized global regulation to address the emergence of unproven stem cells treatments. It is understandable that many people affected by the condition want access to experimental new treatments, especially given the high expectations surrounding the therapeutic potential of stem cells. However, hundreds of clinics around the world offer stem cells transplants which are not only unproven, but highly unlikely to help anyone. European countries have seen a number of controversial stem cells clinics such as the X-Cells Center in Germany and the Stamina Foundation in Italy which, before being shut down by the authorities, highlighted the need for regulation and effective communication.

Falling global travel costs and direct-to-consumer online marketing have driven the growth of the health tourism industry. Some clinics are opening in countries with looser regulations regarding treatment and targeting overseas patients. Many of these clinics offer treatments based on poorly designed trials published in journals with weak peer-review processes to claim legitimacy.

#### **e. Violation of stem cells service laws**

The global stem cells market is expected to reach US 270.5 Billion by 2025, at a compound annual growth rate of 13.8% over the period from 2017 to 2025. All this comes from a report published by Transparency Market Research. The increasing prevalence of

chronic diseases and the increasing investment of pharmaceutical and biopharmaceutical companies in stem cells research are the main driving factors of the stem cells therapy market. This makes the stem cells market a viable investment market.

Stem cells regulation that is difficult to fulfill considering that the regulation is not yet perfect causes many violations that occur because it has not been regulated in detail. Technological advances and the increasing demand for stem cells use have resulted in many stem cells business actors opening up opportunities even though they have not been regulated in regulations.

An example of a stem cells violation case is the discovery of an illegal stem cells service case in the Kemang area in January 2020. Head of the DKI Jakarta Referral Health Service and Health Crisis Section, Sulung Mulia Putra, said that the stem cells business actor, dr. Oeping Handajanto has a valid individual practice license issued by the One Stop Service and Investment Office. However, the clinic where dr. Oeping practicing stem cells at the Hubsch Clinic Ruko Bellepoint, Jalan Kemang Selatan VIII, Mampang Prapatan, Jakarta does not have a permit. Likewise with his certification of expertise in cells injection. Considering the uncovered case of illegal stem cells injection practices, the license to practice dr. Oeping as a general practitioner is in danger of being revoked.

Investigators from the Sub-Directorate of State Security at the Directorate of General Criminal Investigation (Ditreskrim) of the Polda Metro Jaya have arrested three suspects after the raid on an illegal stem cells clinic, Saturday afternoon (13/1) in the Kemang area, South Jakarta.

Three people have been questioned with the initials Y, O, and L. After the results of the examination, their status was raised as suspects and the persons concerned have been detained at the Polda Metro Jaya.

Investigators from the Sub-Directorate of State Security at the Directorate of General Criminal Investigation (Ditreskrim) of the Polda Metro Jaya have sealed a clinic with its address at Ruko Bellepoint, Jalan Kemang Selatan VIII, South Jakarta, for carrying out the practice of injecting stem cells illegally. The disclosure of the illegal clinic started with public reports regarding illegal medical practices using stem cells injection mode without a distribution permit from BPOM. Subsequently, it was found that the agency was illegal. Even though it has been operating for three years in Indonesia.

During the investigation, officers then received information about the existence of stem cells injections in a patient. Investigators again received information about the existence of stem cells injections to patients in the Kemang area, namely at the H Clinic. Then the investigators conducted a hand arrest operation while the activity was taking place. Polda Metro Jaya investigators arrested several people in the operation and named three people as suspects, namely YW (46) as clinic manager, LJ (47) as marketing manager and Dr. OH as general practitioner and clinic owner in charge of injecting patients. During the arrest operation, officers confiscated a number of evidences, such as stem cells from unlicensed Japanese product K, infusion tubes, syringes, antiseptic devices and patient registration.

Based on information from the owner, the company is an abbreviation of Kintaro Cells Power, an innovative Japanese company, which has studied and systematized data on more than 950 studies on the use of mesenchymal stem cells in therapy. They have treated more than 2,000 patients aged 1 to 97 years. They are ready to consult all who seek help, and offer treatment for eligible medical conditions. To date, not a single side effect of using Kintaro cells therapy has been recorded. The world-famous Tokyo Medical University carries out the quality control of the Kintaro cells method; each stem cells pool must have official certification prior to therapy. However, this information certainly will not affect the legality of the services provided by the clinic, considering that the products used do not



have a distribution permit in Indonesia.

Another case after the above case, on January 20, 2020, officers from Sub-Directorate I of the Narcotics Directorate of the Polda Metro Jaya raided a beauty clinic at Rukan Permata Senayan, Jalan Army Student Block E-06, Kebayoran Lama, South Jakarta. The clinic, named De'Eleriz Beauty & Health Center, is suspected of carrying out illegal stem cells injection practices.

Head of Sub-Directorate I of the Metro Jaya Police Narcotics Directorate, AKBP Ahmad Fanani, said that during the raid the police confiscated a number of pieces of evidence. These items are suspected to inject stem cells into patients. There are syringes, serum and others. The suspects, victims and witnesses were then brought to the Polda Metro Jaya for examination.

## 2. Law Enforcement For Illegal Stems Cells Service Violations

Error comes from the word "schuld", which until now has not been officially recognized as a scientific term that has a definite meaning, but has often been used in writings. The definition of error according to Pompe, is that an error has a sign as a disgraceful thing (*verwijtbaarheid*) which in essence does not prevent behavior that is against the law (*der wederrechtelijke gedraging*). In the formulation of positive law, error means having intentional and negligence (*opzet en onachtzaamheid*), and the ability to be responsible (*toerekenbaarheid*).

Errors in a broad sense include intentional, negligence and accountability. All three are subjective elements of the terms of sentencing or if we follow the group that incorporates the element of error in a broad sense into the definition of offense (*strafbaar feit*) as a subjective element of the offense, it is also added that the absence of excuses for forgiveness is also the fourth part of the offense.

Pompe and Jonkers, also include "against the law" as an error in a broad sense in addition to "deliberate" or "error" (*schuld*) and can be accounted for (*toerekeningsvatbaarheid*) or the term Pompe *toerekenbaar*. But according to Pompe, being against the law (*wederrechtelijkheid*) lies outside of breaking the law, while intentional, negligence (*onachtzaamheid*) and being accountable lies in breaking the law. Then intentionally and negligently (*onachtzaamheid*) it must be done against the law in order to fulfill the element of "error" in a broad sense.

Since 1930, the principle of "no crime without guilt" (German: *Keine Strafe ohne Schuld*) was introduced, only those who are guilty or who are accountable to the maker can be punished.

The practice of illegal stem cells injection is a mistake that is suspected to have violated Article 204 paragraph (1) of the Criminal Code and or Article 263 of the Criminal Code and or Article 75 paragraph (1), Article 76 of Law Number 29 of 2004 concerning Medical Practices and or Article 201 in conjunction with Article 198 jo Article 108 of Law Number 36 of 2009 concerning Health and or Article 8 paragraph (1) letter a of Law Number 8 of 1999 concerning Consumer Protection in conjunction with Article 55 and Article 56 of the Criminal Code.

Legislation, both at a lower level and at a higher level, aims to enable the public and the state apparatus to implement them consistently and without discriminating between one community and another. Everyone is seen as equal before the law (equality before the law). However, in its implementation, the Act is often ignored for its application, so that the regulation is not effective. The ineffectiveness of a regulation is caused because the law is vague or unclear, the apparatus is inconsistent or the community does not support the implementation of the regulation. If the Act is implemented properly then the Act is said to

be effective. It is said to be effective because the sound of the law is clear and in its application there is no need for interpretation, the apparatus enforces the law consistently and the people affected by the regulation support it.

**a. Criminal Law Enforcement**

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Referring to Article 204 paragraph (1), what is actually done by illegal stem cells clinics is to use products that are not standardized or do not have a distribution permit from the POM as a product that can be used en masse. This article should not be used to ensnare the perpetrators because it has not been proven that the product used is a dangerous product and there are no victims with defects or deaths due to the use of this stem cells product.

Consumers are parties who in trading activities tend to be seen as having a weaker position than producers of goods and entrepreneurs/traders. Due to the weak position of consumers, legislators have also made efforts to provide legal protection to consumers. One form of consumer protection, namely the protection provided by the Criminal Code (KUHPidana) through Article 204 and Article 205 of the Criminal Code. Article 204 and Article 205 of the Criminal Code relate to goods that are dangerous to people's lives or health, where the goods are sold, distributed, and so on to other people who can be seen as consumers, including patients. The most important difference between Article 204 and Article 205 is that Article 204 is a criminal offense (delict) intentionally (dolus), while Article 205 is a criminal act (delict) of negligence (culpa). This article is generally used for unlawful acts in the form of trading prohibited drugs or liquor because it endangers the health of consumers. In contrast to the use of stem cells, which actually aims to cure the disease of consumers who expect a lot. For this reason, clear regulations are needed so that the purpose of legal protection is achieved.

It is more appropriate if the Article violated by the perpetrators of illegal stem cells service practices is Article 106 of Law No. 36 of 2009 concerning Health which reads:

- 1) Pharmaceutical preparations and medical devices can only be circulated after obtaining a distribution permit
- 2) Marking and information on pharmaceutical preparations and medical devices must meet the requirements for objectivity and completeness and not be misleading
- 3) The government has the authority to revoke the distribution permit and order the withdrawal from circulation of pharmaceutical preparations and medical devices that have obtained a distribution permit, which are later proven not to meet the quality and/or safety and/or usefulness requirements, may be confiscated and destroyed in accordance with the provisions of laws and regulations.

With legal implications, as stated in Article 196 of Law no. 36 of 2009 concerning Health, which reads:

Any person who intentionally produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or benefit, and quality as referred to in Article 98 paragraph (2) and paragraph (3) shall be subject to imprisonment for a maximum of 10 (ten) years and a maximum fine of Rp. 1,000,000,000.00 (one billion rupiah)

The POM Agency regulations that provide guidance on the registration requirements of human cells-based drugs in Indonesia and guidelines for evaluating human cells-based drugs were still in draft form at the time this case emerged. This shows that the regulation for administering the distribution permit of human cells-based drugs is not yet available which causes an urgent need for the right to life of patients with diseases who do not yet have standardized therapy to continue to make efforts to cure in various ways. The element of intent, negligence and accountability in this illegal practice meets the criteria for an unlawful act. However, the unpreparedness of existing regulations can bring health practitioners into conditions of being exposed to legal snares.

The imposition of criminal law against doctors who are made defendants, this depends on the question of whether in doing this act he has a mistake. In explaining the meaning of guilt, the ability to take responsibility is briefly described as a normal, healthy mental state of a person. Accountability for a person in criminal law does not only mean that it is legal to impose a sentence on that person, but can also be fully convinced that it is in the right place to ask for accountability for the crime he has committed.

First of all, criminal liability is a condition that exists in the maker when he commits a crime. Thus, the study was carried out in two directions. First, criminal responsibility is placed in the context of the factual conditions (conditioning facts) of sentencing, therefore carrying out a preventive aspect. Second, criminal liability is a legal consequence. The concept of criminal responsibility relates to the mechanism that determines whether the maker can be convicted, so that it is especially influential for judges. Judges must consider all these aspects, both positively and negatively formulated. The judge must consider this, even if the Prosecutor does not prove it. On the other hand, when the defendant submits a defense based on reasons that erase the guilt, the judge is obliged to go deeper into the matter.

The meaning of intentionality is not explained authentically in the Criminal Code, but in *Memorie Van Toelichting* it is explained that what is meant by intentionality is the will and realizing that an action and its consequences will occur (*Willens enwetens veroorzaken van eangevolg*), meaning that someone who does an act intentionally must will it, and be aware of such actions and/or their consequences. According to Criminal Law, intentionality has several forms/patterns, namely:

- 1) Intentional as an intention (*opzet als oogmerk*), meaning that the occurrence of a certain action or result (in accordance with the formulation of the criminal law) is really a manifestation of the intent or purpose and knowledge of the perpetrator;
- 2) Deliberately with definite awareness or necessity (*opzet bijzekerheids of nood zakelijkheids bewustzijn*), meaning that what is relied on is how far the perpetrator's knowledge or awareness of actions and consequences which are one of the elements of an offense that has occurred;
- 3) Deliberately aware of the possibility (*dolus eventualis*), meaning that what is relied on is the extent to which the perpetrator's knowledge or awareness of prohibited actions and consequences (along with other actions or consequences) may occur;

In an intentional sense, two theories arise, namely the theory of will and the theory of knowledge. According to the theory of will, intentionality is the will that is directed towards the realization of actions as formulated by the law, while according to the theory of knowledge, intentionality is the will to act by knowing the elements required by law;

It is necessary to prove that there was intentionality on the part of the defendant which proves that the defendant understands and is aware of what he has done along with the consequences and the accompanying circumstances; and whether the perpetrator of a criminal act not only wants his action but also realizes that his action is prohibited by law and is threatened with a crime, this intentionality is an inner attitude of the Defendant where to prove whether this criminal act was committed intentionally or not, it can be It is sought from witness statements, evidence, as well as from the testimony of the defendant himself so that from these statements and the presence of evidence it can be concluded whether the act was committed intentionally or not.

Asking doctors to be criminally responsible for medical actions that are suspected to be wrong is not an easy thing because to prove an alleged medical error is not only based on determining the error in the teachings of criminal law. However, to prove the doctor's medical error, he has violated the provisions contained in the Medical Council Regulation No. 4 of 2011 concerning the Professional Discipline of Doctors.

The involvement of the Medical Council in legal issues that ensnare medical personnel. If in the practice of stem cells services there is forgery of letters, then the error is regulated in **Article 263 of the Criminal Code. ("KUHP")** which reads:

- 1) Any person who makes a forged document or falsifies a letter which can give rise to a right, an agreement or debt relief, or which is intended as evidence of something with the intention of using or ordering another person to use the letter as if the contents are true and not falsified, is threatened if such use may result in losses due to falsification of a letter, with a **maximum imprisonment of six years.**
- 2) same punishment , whoever deliberately uses a forged or forged letter pretending to be true, if the use of the letter can cause harm.

From the sound of the provisions of Article 263 of the Criminal Code above, it can be concluded that forgery of letters is a criminal offense punishable by a fairly heavy imprisonment, namely a **maximum of six years in prison .**

This article is not specifically aimed at falsification of letters related to health practices, but is an article that is used for all cases of forgery of letters that cause harm.

If in carrying out illegal stem cells services other workers are involved, then these other workers can be ensnared by criminal law in accordance with the provisions regarding participating in and helping to carry out can be seen in Article 55 (participating in) and Article 56 of the Criminal Code ("KUHP"). (help do):

Article 55 of the Criminal Code:

- 1) Sentenced as a person who commits a criminal event:
  - 1e. The person who does, who orders to do, or participates in doing the act;
  - 2e. A person who by giving, using an agreement, misuses power or influence, violence, threats or deception or by giving an opportunity, effort or information, deliberately induces to do something.
- (2) Regarding the persons referred to in sub 2e, only those actions that they have deliberately persuaded and their consequences can be accounted for.

R. Soesilo explained what is meant by "people who participate in" (medepleger) in Article 55 of the Criminal Code. According to R. Soesilo, "to do" in the sense of the word "to do together". There must be at least two people, namely the person who commits (pleger) and the person who participates in committing (medepleger) criminal events. Here it is requested that the two people all commit the act of execution, thus committing the elements or elements of the event of the criminal act. It is not permissible, for example, to only carry out preparatory actions or actions that are only helpful in nature, because if so, then the person who helps is not considered "medepleger" but is punished as "helping to

do" (medeplichtige) in Article 56 of the Criminal Code.

As for Article 56 of the Criminal Code, R. Soesilo explained that a person "helps to commit" if he intentionally provides the assistance, at the time or before (so not after) the crime is committed. If the assistance is given after the crime has been committed, then the person commits an act of "conspiracy" or "tadah" in violation of Article 480 of the Criminal Code, or a criminal event as referred to in Article 221 of the Criminal Code.

In the explanation of Article 56 of the Criminal Code it is stated that the element of "deliberate" must exist, so that people who by chance without knowing have provided opportunities, efforts, or information to commit the crime are not punished. The "intention" to commit the crime must arise from the person who was given the assistance, opportunity, effort or information. If the intention arises from the person providing the assistance himself, then that person is guilty of "persuading to do" (**uitlokking**).

Quoting the opinion of Hazewinkel-Suringa, Hoge Raad (Netherlands) stated two conditions for the existence of participating in a criminal act, namely: First, conscious cooperation between the participants, which is a common will between them; Second, they must jointly carry out the will.

Furthermore, Prof. Dr. Wirjono Prodjodikoro, SH, explained the difference between "doing" and "helping to do". According to him, based on the theory of subjectivity, there are 2 (two) measures used: The first measure is about the intentional form of the perpetrator, while the second measure is about the interests and goals of the perpetrator.

The measure of intentionality can be; (1) about the will of the perpetrator to actually participate in committing the crime, or only to provide assistance, or (2) the question of the will of the perpetrator to actually achieve the consequences that constitute an element of the crime, or only to participate in or assist if the main actor wants it. Meanwhile, the measure of the same interests or goals is if the actor has his own interests or goals, or only helps to fulfill the interests or to achieve the goals of the main actor.

Furthermore, it is analyzed whether it is included in "committing" a crime or "helping to commit" a crime. In "committing" there is a conscious cooperation between the perpetrators and they jointly carry out the will, the perpetrators have a goal in committing the crime. Whereas in "helping to do", the will of the person helping to do is only to help the main actor achieve his goal, without having a goal of his own.

#### **b. Civil Law Enforcement**

In principle, there are only two types of civil disputes or lawsuits, namely Default and Unlawful Acts (PMH). In the civil law law, it is mentioned in the case of claims against the law. Acts against the law are regulated in **Article 1365 of the Civil Code (KUHPerdara)**, reads :

*"Every act that violates the law and causes harm to others , obliges the person who caused the loss because of his fault to replace the loss ."*

The article implies that the following conditions must be met:

1. The existence of an action (doing or not doing)
2. The act is against the law
3. There is a loss borne by the patient
4. There is a causal relationship between loss and error
5. There is an element of error or omission

The explanation of these conditions are:

- 1) The element of an unlawful act

Acts against the law means an act or action of the perpetrator who violates/against the law. Since 1919, the definition of against the law is not only limited to the law (written law only) but also the unwritten law, as follows:

Violating the law means that the act committed clearly violates the law.

Violating the subjective rights of others, meaning if the actions taken have violated the rights of others which are guaranteed by law (including but not limited to personal rights, freedoms, material rights, honor, good name or other individual rights).

Contrary to the legal obligations of the perpetrator, it means legal obligations, both written and unwritten, including public law.

Contrary to decency, namely moral rules (Article 1335 in conjunction with Article 1337 of the Civil Code)

Contrary to the prudence that should be in society. This criterion is based on unwritten law (relative in nature). That is, an act that is carried out contrary to good / proper attitude in society to pay attention to the interests of others.

Elements of error

There are 2 (two) errors, it could be intentional or due to negligence. Deliberate means that there is an awareness that normal people know that the consequences of their actions will harm others. Meanwhile, negligence means that there is an act of ignoring something that should be done, or not being careful or careful so that it causes harm to others. However, sometimes a certain situation can eliminate the element of error, for example in the case of a forced situation (*overmacht*) or the perpetrator is not mentally healthy (crazy).

The element of a causal relationship between loss and action (Causality Relationship)

That is, there is a causal relationship between the actions taken and the consequences that arise. For example, the losses that occur are caused by the actions of the perpetrator or in other words, the loss will not occur if the perpetrator does not commit the unlawful act.

Elements of loss

As a result of the perpetrator's actions cause losses. Losses here are divided into 2 (two) namely material and immaterial. Material, for example, loss due to a car crash, loss of profit, cost of goods, costs, and others. Immaterial such as fear, disappointment, regret, illness, and loss of enthusiasm for life which in practice will be valued in the form of money.

The provision of compensation according to the Civil Code is as follows:

- 1) Compensation for all unlawful acts (Article 1365 of the Civil Code);
- 2) Compensation for actions committed by other people (Article 1367 of the Civil Code). Article 1367 paragraph (1) of the Civil Code, a person is not only responsible for losses caused by his own actions, but also for losses caused by the actions of people who are his dependents or caused by goods that are under his control (*vicarious liability*).
- 3) Compensation for the owner of the property (Article 1368 of the Civil Code)
- 4) Compensation for the owner of the collapsed building (Article 1369 of the Civil Code)
- 5) Compensation for the family left behind by the person killed (Article 1370 of the Civil Code)
- 6) Compensation due to injuries or limb defects (Article 1371 of the Civil Code)
- 7) Compensation for acts of humiliation (Article 1372 of the Civil Code)

The Civil Code does not regulate the issue of compensation that must be paid due to unlawful acts while Article 1243 of the Civil Code makes provisions regarding compensation due to Default. So according to jurisprudence, the provisions for compensation due to default can be applied to determine compensation due to unlawful acts. Based on the description above, it can be understood that the elements of PMH can be divided into 4 elements; *First* : the element of an unlawful act, *Second* : the element of error, *Third* : the element of a causal relationship, and *Fourth* : the element of loss.

In addition to civil law due to violating Article 201 of Law number 36 of 2009 concerning Health, it also contains criminal elements:

The criminal acts as referred to in Article 190, Article 191, Article 192, Article 196, Article 197, Article 198 and Article 200 are committed by corporations, in addition to imprisonment and fines for their management, the punishment that can be imposed on corporations is in the form of fines with a weight of 3 (three) times the fine as referred to in Article 190 paragraph (1), Article 191, Article 192, Article 196, Article 197, Article 198, Article 199, and Article 200

In addition to the fine as referred to in paragraph (1), corporations may be subject to additional penalties in the form of:

**Revocation of business license and/or Revocation of legal entity status**

Law 8 of 1999 concerning Consumer Protection, its formulation refers to the national development philosophy that national development, including the development of laws that provide protection to consumers, is in the context of building a complete Indonesian human being based on the state philosophy of the Republic of Indonesia, namely the state foundation of Pancasila and the state constitution, the 1945 Constitution.

The definition of Consumer in the Consumer Protection Law is the End Consumer. This is explained in the Elucidation of Article 1 number 2 of Law 8 of 1999 concerning Consumer Protection, namely that in the economic literature the terms end consumers and intermediate consumers are known. End consumers are end users or beneficiaries of a product, while intermediate consumers are consumers who use a product as part of the production process of another product. The definition of consumer in this law is the final consumer.

The principles of Consumer Protection in Law 8 of 1999 concerning Consumer Protection, namely:

- The principle of benefit is intended to mandate that all efforts in the implementation of consumer protection must provide the maximum benefit to the interests of consumers and business actors as a whole.
- The principle of justice is intended so that the participation of all people can be realized maximally and provide opportunities for consumers and business actors to obtain their rights and carry out their obligations fairly.
- The principle of balance is intended to provide a balance between the interests of consumers, business actors, and the government in a material or spiritual sense.
- The principle of consumer safety and security is intended to provide guarantees for security and safety to consumers in the use, use and utilization of goods and/or services that are consumed or used.
- The principle of legal certainty is intended so that both business actors and consumers obey the law and obtain justice in the implementation of consumer protection, and the state guarantees legal certainty.

According to Lawrence Meir Friedman, a legal sociologist from Stanford University, the success or failure of law enforcement depends on: Legal Substance, Legal Structure/Legal Institution and Legal Culture.

1. Legal substance

Legal substance can be said as norms, rules, and real human behavior that is in the system, in the substance of the law there is the term "product" which is a decision that has just been drawn up and has just been made, which here emphasizes that the law will be made if through the first event. For this reason, it is necessary to make laws that are in accordance with violations in cases of violations in stem cells services which are certainly different from other cases.

As written in Article 1 of the Criminal Code, it is determined "no criminal act can be punished if there are no rules governing it", actually with this statement a law violator

cannot be prosecuted for actions that violate the law itself. The substance of the law also includes living law, not just the rules contained in law books. With the existence of legal regulations that are in accordance with the violation of the case at hand, wherever the unlawful act occurs, it will be prosecuted with the same law.

Violations in stem cells services cannot be fully equated with law enforcement against violations of Article 196 of Law no. 36 of 2009 concerning Health, which is charged with 10 years imprisonment and a maximum fine of 1 billion rupiah, as in the case of the defendant drh. YHP in January 2020, a lecturer who did a lot of research on stem cells and carried out stem cells treatment for "desperate" group patients who had received a verdict that they would not recover from their illness. The patient eventually recovered and did not pay for the stem cells services provided.

## 2. Legal structure

Legal structure, namely the framework of a permanent form of the legal system that keeps the process within its boundaries. The Structural System determines whether or not the law is implemented properly. The legal structure based on Law no. 8 of 1981 includes; starting from the Police, the Prosecutor's Office, the Court and the Criminal Implementing Agency (Lapas). In addition, in violation of the law related to health, it is necessary to involve a legal structure in accordance with the Regulation of the Indonesian Medical Council Number 4 of 2011 concerning the Professional Discipline of Doctors.

The authority of law enforcement agencies is guaranteed by law so that in carrying out their duties and responsibilities, they are free from the influence of government power and other influences. If the regulations are good, but the quality of law enforcement is low, there will be problems. Likewise, if the regulations are poor while the quality of law enforcement is good, the possibility of problems arising is still open. What is no less important is that law enforcement officers in carrying out law enforcement must have a level of ability or professionalism as well as the availability of adequate funds, human resources, facilities and infrastructure.

## 3. Legal Culture

This legal culture is also interpreted as an atmosphere of social thought and social power that determines how the law is used, avoided, or misused. Furthermore, Friedman formulates legal culture as attitudes and values that are related to law and the legal system, along with attitudes and values that have a positive or negative influence on behavior related to law. Likewise, the pleasure or displeasure of litigation is part of the legal culture. Therefore, what is called legal culture is nothing but the overall factors that determine how the legal system acquires its logical place within the cultural framework of the general public. So in short it can be said that the so-called legal culture is the overall attitude of the citizens and the value system that exists in society which will determine how the law should apply in the society concerned. The operation of a legal system in society (law in action), will not be separated from the influence of aspects of values and attitudes, which provide an understanding of the workings of the legal system.

The more widespread violations that occur in the process of enforcing criminal law by law enforcement officials, it seems as if the community has lost confidence in the function of criminal law in solving problems in society. In the collision, the principle of equality before the law and the presumption of innocence, which try to fortify law enforcement officials in carrying out their activities, have become commonplace. In fact, not infrequently on several occasions the work of criminal law in society raises what are called criminogenic and victimogenic factors.

This condition is further exacerbated by the inability of the criminal law to work substantively (both material and formal) in balancing the development of a society that is increasingly diverse in style and color. Criticism of criminal law is always aimed at the



inadequacy of criminal law as a tool to achieve substantive justice.

The relationship between the three elements of the legal system, such as mechanical work. Structure is like a machine, substance is what machines do and produce, while legal culture is anything or anyone who decides to turn on and turn off the machine, and decides how the machine is used. Associated with the legal system in Indonesia, Friedman's theory can be used as a benchmark in measuring the law enforcement process in Indonesia. The police are part of the structure along with the organs of prosecutors, judges, advocates, and correctional institutions as well as the health legal structure. The interaction between these components of law enforcement determines the strength of the legal structure. Therefore, law enforcement in cases of violations of stem cells services needs to be made an appropriate legal structure, considering the current law is still not firm in providing an elaboration of the regulations that must be obeyed. However, the enforcement of the law is not only determined by the strength of the structure, but is also related to the legal culture in society. However, until now the three elements as stated by Friedman have not been implemented properly, especially in the legal structure and legal culture.

### **3. Regulations Need To Be Prepared To Provide Safe And Effective Stem Cells Services**

The increasing reach of the internet and social media continues to complicate matters. Global, direct-to-patient marketing of unproven treatments is a major concern. Stronger global and national regulatory guidelines are needed, along with public outreach initiatives from researchers, to help address these issues before undermining the legitimacy of the stem cells research arena.

The recent controversy in the field of stem cells therapy has prompted demands for more stringent regulations. For example, the X-Cells Center in Germany targets an international audience, and exploits legal loopholes to offer their unproven treatment. It was only after the deaths of two children that criticism of the center became strong enough to force its closure.

The public's need for effective new treatments is strong, driven in part by overly optimistic media coverage of the many unapproved therapies. Generally standardized therapy requires a lengthy consent process, restricting access from a few patients until evidence is strong. This can lead to the perception that potential healing efforts are being held back by the bureaucracy. Many protest actions were thrown by various institutions under the pretext of emergency rescue, but as long as this condition is not accommodated in the regulations that regulate it, it cannot be considered legal treatment.

Despite many calls to tackle the marketing of unproven stem cells treatments directly to consumers, they have not succeeded in effectively stopping this activity. The most important thing is the need to build global regulations. Some of the successes of global regulation in the pharmaceutical sector have been made possible by the International Council for Harmonization (ICH), which brings together national regulatory authorities to decide international standards for the manufacture and testing of small molecule drugs. Similar transnational research could be played by ICH in developing global regulations for cells and tissue-based therapies.

WHO needs to coordinate with competent national authorities to disseminate guidelines on the responsible clinical use of human cells and tissues, as is now being done for drugs and medical devices. WHO also plays a role in advising countries on the development of their own legal standards of medical practice. Success will no doubt depend on the cooperation of many countries to effectively enforce the new regulations.

Researchers must communicate their research results effectively to the public. This is necessary so that people do not become victims of unproven and unethical practices.

There is a need to regulate the regulation of stem cells treatment advertisements at the local level. It also needs to work out how local medical agencies develop and implement practical guidelines on how doctors advertise care.

Stem cells therapy remains a promising and rapidly developing field, but it is not a miracle cure. In fact, current stem cells therapies don't live up to the promises many had hoped for. Although it is an important and growing field, the number of approved and successful stem cells treatments remains low. Until greater global regulations are put in place, marketed direct-to-consumer therapies must be treated on a scientific basis.

There are many loopholes that make doctors who practice stem cells services ensnared by the law because the existing laws and regulations have not been made comprehensively so that they are easy to be charged with various articles of violation, both criminal and civil, even though to determine the criteria for doctors to make medical errors, they do not only rely on mistakes. only in criminal law. Due to the criteria for determining a doctor's medical error, one must first pass a series of proofs within the scope of medical discipline and medical ethics, all of which are carried out undergoing examinations according to the Indonesian Medical Council Regulation Number 4 of 2011 concerning Professional Discipline of Doctors, which is the most important and fundamental element. to prove whether the doctor has made a medical error.

The MKEK's duty to guide, supervise, and evaluate the implementation of medical ethics is not in line with the noble ideals of the medical profession. Not all cases that are considered unlawful acts committed by doctors are brought to the MKEK which is under the auspices of the Indonesian Doctors Association (IDI), both at the central level and at the branch level.

The task of the judiciary for medical personnel is mostly taken over by the police rather than the professional court, the development of professional ethics and/or institutional tasks carried out by the MKEK are tiered from the region to the submission to the central level.

Strict regulations for comprehensive medical personnel on the provision of stem cells services are urgently needed to protect doctors and patients who use them. The coordinating relationship between the MKEK institutionally and the handling of cases with medical disciplinary institutions or councils or law enforcement according to their current jurisdictional level seems to have not been well coordinated.

Ideally, to determine whether there are mistakes made by doctors and dentists in the application of medical and dental disciplines, and to impose sanctions (see Article 1 point 14 of the Medical Practice Law) is the authority of the MKDKI (Article 55 paragraph (1) of the Medical Practice Law). MKEK must be involved in enforcing medical professional ethics, while MKDKI is the institution that has the authority to determine whether there is an error in the application of medical discipline and impose sanctions on it.

In order to obtain clarity of legal protection for health workers in stem cells and/or cells services, a tiered and comprehensive regulation is needed to regulate stem cells services in Indonesia. The order of laws and regulations in Indonesia has undergone 4 (four) changes since independence, as regulated in MPRS Decree Number XX/MPRS/1966, MPR Decree Number III/MPR/2000, Law no. 10 of 2004, and Law no. 12 of 2011. The four statutory regulations have quite striking similarities and differences.

The latest hierarchical arrangement is based on Law no. 12 of 2011 has provided improvements to Law no. 10 of 2004 which restores the position of the MPR Decree in the hierarchy of laws and regulations with the following composition:

1. The 1945 Constitution of the Republic of Indonesia;

2. Decree of the People's Consultative Assembly;
3. Laws/Government Regulations in Lieu of Laws;
4. Government Regulations;
5. Presidential Regulation;
6. Provincial Regulations; and
7. Regency/City Regional Regulations.

What is the position of Ministerial Regulations and State Institutions at the Ministry level. The Ministerial Regulation has the position of other regulations in Law no. 12 of 2011. Although it is not specifically included in the hierarchy, its existence is still recognized and even in its implementation. Ministerial regulations have a higher position than regional regulations because in the era of Law no. 23 of 2014, regional regulations were canceled through a Ministerial Regulation (Permendagri). Ministerial Regulation as a type of regulation that is regulating (regeling) and has a higher position than a Ministerial Decree (beschikking). Ministerial regulations are central regulations made by the central government which are in the nature of implementing higher regulations and at the same time being the implementation of central authority which has a higher position than regional regulations. Therefore, every stipulation of regional regulations must refer to ministerial regulations.

The formation of ministerial regulations itself is motivated by government policies that need to be stated in the form of implementing regulations for higher regulations, therefore the Minister or ministerial-level officials may be given the authority to make implementing regulations.

The legislation on stem cells services is currently regulated in Law number 26 of 2009 concerning Health, but there is no Government Regulation and Presidential Regulation that underlies it. From the hierarchy of laws and regulations through two levels above it to enter the Regulation of the Minister of Health. With the comprehensive regulation of stem cells services, it is hoped that legal protection and certainty for both service providers and recipients will be able to run fairly and wisely

## CONCLUSION

Based on the research on stem cells services that the authors have done, it can be concluded that:

1. After more than ten years of enactment of Article 29 of Law Number 36 of 2009 concerning Health, the operational arrangements with the regulations under the law have not been completed. As is known, the issue of stem cells has been regulated in Article 70 of the Health Law, which reads:
  - 1) The use of stem cells can only be used for the purpose of curing disease and restoring health, and it is prohibited to use them for reproductive purposes;
  - 2) The stem cells as referred to in paragraph (1) may not originate from embryonic stem cells.
  - 3) Further provisions regarding the use of stem cells as referred to in paragraph (1) and paragraph (2) shall be regulated by a Ministerial Regulation.

Considering that laws only regulate big and global matters, the presence of laws under them is very important and strategic so that stem cells development can move forward to meet national health needs. For certain operational levels, revisions to Permenkes number 32 of 2018. Moreover, this Permenkes does not specify in detail the procedure for obtaining competency recognition for personnel who can do it so that until now no one has certification to have stem cells governance competence in the country. Likewise, the stipulation of hospitals that are allowed to conduct stem cells

research-based research is only limited to 11 government hospitals. This seems less objective in developing stem cells technology, not only because of limited funding but also limited human resources and strong personnel. The experience so far is that hospitals that get permits tend to be more inclined to carry out research from their own hospitals. This can lead to a tendency to dull the spirit and dynamics of stem cells scientific development in Indonesia.

2. The current regulation of stem cells in a hierarchical and legislative manner is incomplete and not comprehensive so that it does not accommodate the orientation of stem cells technology development which moves very fast and has positive progress. The implementation of the law in stem cells regulation must be accommodated by hierarchical laws and regulations starting from Law No. 36 of 2009 concerning Health, not yet followed by Government Regulations or Presidential Regulations. There are only Ministerial Regulations below which are also not yet complete and comprehensive in regulating the problem. This can lead to problems in the future, including law enforcement if there are violations committed by the perpetrators in the field.

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