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Legality of therapeutic contract of stem cell treatment in Indonesia

Ahdiana Yuni Lestari[1], Danang Wahyu Muhammad[1], Izzy Al Kautsar[3], Siti Ismijati Jenie[1]
[1]Department of Civil Law, Faculty of Law, Universitas Muhammadiyah Yogyakarta, Yogyakarta, Indonesia
[3]Department of Civil Law, Universitas Sebelas Maret, Surakarta, Indonesia

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ABSTRACT

This study analyzed the purposes and functions of stem cell treatment arrangements in Indonesian national law and then describe the characteristics of therapeutic agreements between patients and elements of health services against the legal terms of the agreement based on the Civil Code. This study used a normative juridical research method. The results of this study are: i) in terms of stem cell treatment procedures, only some can get services and treatment because the procedure is very complicated and lengthy. Hence, the purpose and function of regulating the implementation of stem cell treatment in Indonesia are to provide legal certainty and protection law to the public and health service providers; ii) the conditions for the validity of a stem cell Therapeutic agreement must be based on the criteria specified in Article 1,320 of the Civil Code, then the elements of the parties that bind themselves; the skills of the parties; particular object, and lawful cause must be clear, and iii) the type of therapeutic contract that can maintain the honor of the parties is the "three in one" model. However, this model currently needs to be improved in Indonesia because of the novelty of the regulatory framework.

Corresponding Author:

Ahdiana Yuni Lestari
Faculty of Law, Unversitas Muhammadiyah Yogyakarta, Yogyakarta, Indonesia
Tamantirto, Bantul, Yogyakarta
Email: Ahdianayunilestari@umy.ac.id

1. INTRODUCTION

Disease treatment was done conventionally with biotechnology research development by administering drugs containing chemical substances. However, with stem cell biotechnology, disease healing and health restoration can be done through stem cells [1]. The development of stem cell therapy is directed at healing degenerative diseases and various other types of diseases related to the body's cell tissue system that can be regenerated so that the possibility of recovery is much greater [2].

Various chemical drugs have been approved for treating patients with the disease, but most of these treatments are costly and have an inadequate response and many side effects. Stem cell therapy modulates immune system responses, and anti-inflammatory drugs can be used to treat patients with the disease. Gene therapy or genetic manipulation of stem cells is considered one of the promising strategies in treating patients. The use of stem cells manipulated by genes that products can be used to treat disease, including the newest cytokines or immunogenic proteins of hepatitis C, appears to be valid [3].

According to Article 64 and Article 70 of Law Number 36/2009 concerning Health, treating diseases with stem cells has obtained legality. Furthermore, it is also regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 833/MENKES/ PER/IX/2009 concerning Implementation of Stem Cell Services; jo Decree of the Minister of Health of the Republic of Indonesia Number 834/MENKES/SK/IX/2009 regarding Guidelines for the Implementation of Stem Cell Medical Services; and

Regulation of the Minister of Health of the Republic of Indonesia number 48 /2012 regarding the Operation of Cord Blood Stem Cell Bank; also the Regulation of the Minister of Health of the Republic of Indonesia Number 32/2012 concerning the Implementation of Stem Cell. Based on these regulations, it can be seen that stem cells are cells of the human body with a remarkable ability to self-regenerate/self-renewal and able to differentiate into other cells [4]. The stem cells used for treatment or recovery are non-embryonic, namely adult stem cells derived from cord blood, bone marrow (Bone Marrow Punction), peripheral blood, and other body tissues [5]. Expert doctors carry out treatment of several diseases with stem cells at hospitals that have been appointed by the government as stipulated in the Decree of the Minister of Health of the Republic of Indonesia Number 32/2014 concerning the Establishment of a Hospital for the Development of Medical Services Research and Education Tissue and Stem Cell Banks [6]. In contrast to some countries, where they do not regulate the extent of the hospital's role in stem cell treatment, but as long as the health provider has sufficient competence and adequate facilities, it is allowed to carry out the medical action. Treatment with these stem cells carries a high risk [7]. In fact, in Indonesia, treatment efforts with stem cells bring new hope to treating patients suffering from degenerative diseases that are very difficult to treat. However, on the other hand, there is a negative side, namely, causing problems related to ethical norms, religion, and law [8]. Issues in ethics and religion include whether embryonic and non-embryonic stem cells can be used for treatment and research. Problems in the legal field include the embryo's legal status and whether the embryo is a legal subject or legal object.

Treatment of a disease with stem cells carried out by doctors to patients in a hospital is an example of a therapeutic contract. Doctors, patients, and hospitals are subjects of medical law. The legal relationship between doctors, patients, and hospitals in treating diseases with stem cells is within the scope of civil law [9]. The contractual relationship occurs because the parties, namely the doctor and the patient, are believed to have freedom. The two parties then enter an agreement where each party must perform its role or function. The role is in the form of rights and obligations. The engagement is called a medical engagement, a medical contract, or a therapeutic contract because it aims to cure a disease [10]. Therefore, medical practice is a service that provides assistance or assistance based on the patient's trust in the doctor and is not a mere business relationship under specific expertise and skills in the field of medicine. The achievement of a therapeutic contract is not a result to be achieved (resultats verbintenis) but a genuine effort (Inspanning verbintenis).

Nevertheless, there are some problems with therapeutic contracts in Indonesia: i) non-disclosure of information that is the right of a patient; ii) diagnostic discrepancy; and iii) unilateral approval of medical action. Patients will tend to obey what a doctor orders because, due to their ignorance, the doctor does not explain in detail related to patient rights as stated in Article 45 of Law number 29 of 2004 concerning Medical Practice in conjunction with Permenkes 290 of 2008 regarding approval of medical action, iv) In the case of surgery, the doctor or nurse usually offers the consent form only, and the patient only needs to sign without reading it first. In the medical action approval form, the doctor, patient, and witness signing is carried out in multiple assemblies. Every process of stem cell treatment must be written approval for medical action. For example, at the time of stem cell collection, during the clinical application, and therapeutic services.

What can be achieved with technology is not necessarily acceptable to religion and the laws in society [11]. Transplant therapy is a problem that is quite complex in various fields of study. Transplant therapy uses a multidisciplinary approach, such as medicine, biology, law, ethics, and religion [12]. In fact, in Indonesia, treatment with stem cells brings new hope to treating patients suffering from degenerative diseases, which have been very difficult to treat. However, on the other hand, there is a negative side, causing problems related to ethical norms, religion, and law. Regulations regarding treating diseases with stem cells in Indonesia still need to be completed, including a review of the use of stem cells in the civil aspect and an explanation of the efforts/actions of medical services with stem cells from a legal perspective.

This study is based on various articles that have examined the status of stem cells from law perspective and the relationship between a health provider and patients. Mishra [13] stated that there are issues in ethics and religion, including whether embryonic and non-embryonic stem cells can be used for treatment and research. Problems in the legal field, such as the embryo's legal status, Rivron [14] debating whether the embryo is a legal subject or legal object. Waldby *et al.* [15] stated that the relationship between doctors and patients always has something to do with the interest in curing diseases and saving human lives. Hence, the relationship between them in stem cell treatment is unique because there is a dependence on the patient to trust the doctor's expertise in curing or saving efforts. Caulfield and Murdoch [16] stated that some treatment relies on the practitioner having obtained full informed consent from the patient; this ethics of the medical profession strongly influences the doctor-patient relationship as a consequence of the professional obligations that provide boundaries, patients demands for established healthcare forms have conventionally been conciliated with the help of doctor's role in defining the demand in the form of 'clinical need' [17]. Stem cell treatment is contained in the moral principles of the profession; these obligations arising in therapeutic contracts regarding treatment with stem cells for health providers must be based on the principles of autonomy, beneficence, non-maleficence, and justice [18].

Technological advancements impact ethical/moral values, religion, law, society, culture, and other aspects. Legal rules regarding the therapy of stem cells vary from country to country and often change with changes in cultural norms and the availability of treatment or medical action. Due to the sensitivity of this issue, clear restrictions and procedures must always be applicable without considering their legal status. Therefore, problems related to stem cell therapy will continue to be debated. From a legal perspective, there needs to be a clear and complete arrangement regarding applying stem cell therapy, so the problem formulation includes: i) What is the purpose and function of stem cell medical services regulation in Indonesia? ii) How is the legality of informed consent in stem cell health services viewed from the perspective of civil law? iii) what is the legal policy of stem cell treatment in several countries, and what is an effective therapeutic contract model?

2. METHOD

This research used a normative juridical research method with a statutory and concept approach. First, this study examines the purpose and function of the law to analyze the urgency of the national regulation of stem cell services in Indonesia. Then describes the concept of an agreement based on the Civil Code to analyze the legality of the therapeutic agreement for stem cell treatment in health care practice with patients and examines legal studies.

The data collection technique used in this paper is a document study technique because this paper departs from a normative premise. Document study techniques will assist in analyzing the certainty of reliable and appropriate data sources used to determine research objectives [19]. The source of data in this paper is obtained from secondary data consisting of primary and secondary legal materials. The primary legal materials in this paper the Civil Code, the Health Act, and the Minister of Health Regulation. The secondary legal materials used are legal books and articles relevant to legal issues and are analytically descriptive.

3. RESULTS AND DISCUSSION

3.1. The purpose and functions of legal regulatory of stem cell health services in Indonesia

Stem cells can only be used for the benefit of medical services for the donors themselves or other people or research and scientific development purposes with the approval of the donor concerned [7]. Every stem cell collection from a donor must obtain written approval from the donor and be carried out under the provisions of the legislation by a hospital that already has the capability and requirements in stem cell medical services that the government has appointed [20]. Health workers with authority can only collect and deliver specimens or parts of body organs. The rules are found in the Decree of the Minister of Health of the Republic of Indonesia Number 32 of 2014 concerning establishing a Central Hospital for the Development of Medical Research and Education Services for Banks Tissues and Stem Cells.

Law Number 36 of 2009 concerning Health is a legal basis for regulating stem cells. More detailed arrangements are in the Regulation of the Minister of Health of the Republic of Indonesia Number 833/ MENKES/PER/IX/2009 concerning the Implementation of Stem Cell Services and Regulation of the Minister of Health of the Republic of Indonesia Number 834/MENKES/SK/IX/2009 concerning Guidelines for the Implementation of Stem Cell Medical Services. However, these two regulations were declared no longer valid after the issuance of the Regulation of the Minister of Health of the Republic of Indonesia Number 32 of 2014 concerning the Establishment of a Central Hospital for the Development of Medical Services for Research and Education of Tissue and Stem Cell Banks and the Regulation of the Minister of Health of the Republic of Indonesia Number 48 of 2012 concerning the Implementation of Cord Blood Stem Cell Banks Center. There are several problems related to these stem cells. Therefore, the government needs to regulate them. According to Innaka [21] in her dissertation, some of these problems as shown in Table 1.

Table 1. Several problems related to stem cells

Variables	Problem
Ethic risks	Most stem cell research is carried out using stem cells derived from embryos.
Probability	The probability that babies with stem cells will use them for non-degenerative diseases is relatively tiny; treating leukemia, for example, is only 0.5% probability, even if the baby can survive 70 years.
Promotion	The existence of excessive promotion by the Stem Cell Bank that cannot be eliminated can cause harm to the community.
Health providers	There is still limited understanding of health providers regarding stem cell services as a whole
Expensive cost	Stem cell therapy is still expensive
Limited Facilities	There still needs to be more facilities and infrastructure regarding stem cell services.

The main hospital appointed by the government is based on the Regulation of the Minister of Health of the Republic of Indonesia Number 32 of 2014 concerning the Establishment of a Central Hospital for the Development of Medical Services, Research, and Education of Tissue and Stem Cell Banks. Thus, stem cell collection can only be carried out by medical personnel with expertise and competence, following established professional standards and standard operating procedures and adhering to donor safety and professional ethics [22]. The medical personnal in question is a doctor, as stipulated in Law Number 29 of 2004 concerning Medical Practice in conjunction with Law Number 36 of 2014 concerning Health Workers.

Stem cells taken from donors can be stored at the Hospital Stem Cell Bank or at a Stem Cell Bank outside the hospital, which has received permission from the Minister of Health with a written agreement. Each stem cell medical service facility must record and report all activities related to the donation, collection, management, storage, distribution, and administration of stem cells in providing stem cell services [23]. The Minister's guidance and supervision of stem cell medical services are carried out by the Health/City Office and Professional Organizations according to their respective duties, functions, and responsibilities, assisted by the National Stem Cell Committee [21]. The Minister may take administrative sanctions against health workers and health facilities who violate the provisions of the applicable legislation through verbal warnings, written warnings up to revocation of practice licenses, and permits for stem cell service provision. The existence of stem cell therapy is a manifestation of the development and discoveries of humankind. The state is here to provide sanctions for those who deviate from a form of human development policy in the health sector to protect many people's lives [24]. This sanction is under the Regulation of the Minister of Health of the Republic of Indonesia Number 833/MENKES/PER/IX/2009 concerning the Implementation of Stem Cell Services.

Stem cell medical services based on the Decree of the Minister of Health of the Republic of Indonesia Number 834/MENKES/PER/IX/2009 concerning Guidelines for the Implementation of Stem Cell Medical Services, stem cell medical service efforts are carried out with the following principles: i) conducted on a network basis between stem cell installations, designated teaching hospitals, and stem cell banks; ii) services are carried out according to medical and bioethical professional standards; iii) the available equipment must meet the requirements; iv) all actions must be well documented and have an evaluation and quality control system.

A person who will follow a stem cell program, whether taking, storing, or using, must go through several stages. There are two regulations regarding the implementation of stem cell banks, namely the Regulation of the Minister of Health of the Republic of Indonesia Number 48 of 2012 concerning the Operation of Cord Blood Stem Cell Banks and the Regulation of the Minister of Health of the Republic of Indonesia Number 62 of 2013 concerning the Implementation of Tissue or Cell Banks.

The purpose of regulating the operation of stem cell banks is to provide legal certainty and protection to the public and the operating bank [25]. The purpose of legal certainty is one of the law's goals in a broad sense, namely justice, certainty, and expediency [26]. These three legal goals can be achieved at different times. If the goal of legal certainty is prioritized, the other two objectives are ruled out, and vice versa. The purpose of the regulation in two Regulations of the Minister of Health of the Republic of Indonesia is to prioritize legal certainty because the function of law is to protect human interests. In its function of protecting human interests, the law has a purpose. The law has a goal to be achieved. The primary purpose of the law is to create an orderly social order and create order and balance. Human interests will be protected by achieving order in society [27].

In the literature, there are several theories about the purpose of the law, namely ethical theory, utility theory, and mixed theory. According to ethical theory, the purpose of the law is solely for justice. Our ethical beliefs determine the content of the law about what is fair and what is not. In other words, the law, according to this theory, aims for justice. The essence of justice is an assessment of treatment or action by reviewing it with a norm that exceeds other norms according to a subjective view [28]. Two parties are involved: the party who treats and receives the treatment. In general, justice is an assessment only seen by the party receiving the treatment, but two parties should see this justice. Regarding the content of justice, Aristotle distinguishes between two types of justice, namely justitia distributiva and Justitia commutative. Distributive justice demands that everyone gets what his or her due is. This share is different for each person, depending on his wealth, birth, education, and ability. What is considered fair here is if everyone gets their right or share proportionally considering education, position, and ability. This distributive justice is the duty of the government towards its citizens, determining what can be demanded by its citizens. This distributive justice is the obligation of legislators to be considered in drafting laws. This justice gives to every one according to his merit or ability. Justitia commutative gives to everyone equally. Thus, what is required here is equality. What is fair here is if everyone is treated equally regardless of position. If distributive justice is a matter for legislators, commutative justice is for judges. According to this utilitarian theory, the law wants to guarantee the greatest happiness for humans in the most significant number of people (the greatest good of the greatest number). In essence, according to the utilitarian theory, the purpose of the law is the benefit of producing the most incredible pleasure or happiness for the most significant number of people [29].

The primary and first purpose of the law is in order. This need for order is a fundamental condition for the existence of an orderly human society. In addition, the purpose of the law is an achievement of justice, which varies in content according to society. The law here must protect human interests so as not to be disturbed. The law will consider which is greater and which one is not because the law aims to ensure legal certainty in the community's life [30]. The purpose of the law is legal certainty, justice, and benefits, but sometimes justice must be sacrificed to achieve benefits. When it comes to procedures and treatment using stem cells, only some can get services and treatment because the procedure to use stem cells is relatively very expensive. Only people who have a very strong (rich) economy can follow and use stem cell treatment. According to Aristotle, the regulation regarding stem cells as an alternative treatment applies to the theory of distributive justice.

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3.2. The legality of informed consent on stem cell (health services) from the perspective of Indonesia civil law

The agreement between the health provider and the health workers is not included in the medical agreement with the patient. However, the legal relationship arising from the agreement affects the patient agreement [33], especially on the legal liability of the health worker. Juridically, the doctor-patient relationship in treating diseases with stem cells is an example of a therapeutic contract. As described in the previous chapter, some theories can be applied in therapeutic contracts. The therapeutic contract between the doctor and patient contains mutual rights and obligations for both parties to the agreement [34]. This mutual right means that what is the doctor's right is the patient's obligation, and what is the doctor's obligation is the patient's right [35]. Therefore, the relationship between doctors and patients in hospitals is a civil relationship regulated in Book III of the Civil Code.

The legal relationship between a doctor and a patient can legally be included in an agreement or contract category, this kind of contract is a manifestation of parties interest [36]. Where the first party commits

itself to provide services, the second party accepts the provision of these services. Patients who ask the doctor to be given treatment services after the doctor accepts to provide their services [37]. According to Siti Ismijati Jennie, to find out the civil nature of the doctor-patient relationship can be seen from the characteristics of therapeutic contracts as follows: [22] i) in the agreement, two parties bind themselves; ii) one party requests the other party's services to cure the disease he suffers by making healing efforts; iii) the party requested his services as an expert in healing the disease; iv) in return, the party requesting the service is willing to provide an honorarium based on the rate set by the party performing the service; The method used to achieve the objectives of this agreement is entirely left to the party requested to perform the service.

Based on the earlier characteristics, therapeutic contracts can be categorized as agreements to perform particular services regulated in Book III, Chapter 7, Article 1,601 of the Civil Code, an agreement to perform particular services is a consensual agreement, namely an agreement that is formed/born with the achievement of an agreement between the parties who bind themselves [38], thus therapeutic contract is also a consensual agreement; [39] consequently, this agreement is an agreement that is free of form. In this kind of agreement, the parties can express their agreement in a written or oral agreement. The parties may choose an authentic or private deed if a written form is chosen. Usually, a therapeutic contract takes the form of an oral agreement. The therapeutic contract can be qualified as a named agreement based on the characteristics above. A named agreement (become contract or nominate contract) is an agreement regulated in law and named by the legislator.

Two types of engagements arise from this therapeutic contract, [22] namely: i) *Inspannings Verbintenis*, which is an engagement that must be carried out with care and effort. In this engagement, the promised achievement is the maximum effort or effort that the doctor must make to cure his patient. Efforts are made to follow the standards of the medical profession of doctors. Because the achievements are in the form of efforts, the results are uncertain; ii) *Resultaat Verbintenis*, an engagement whose performance results in something particular. Thus, the relationship between doctors and patients in medical services civilly using stem cells can be qualified as a named agreement and give rise to an inspanning verbintenis type of engagement. Doctors will try their best to cure patients using stem cells.

With the therapeutic contract mentioned above, doctors and patients have received legal protection that ensures their goals are fulfilled [40]. The perspective of civil law, a therapeutic contract is an agreement to perform a particular service as regulated in Article 1,601 of the Civil Code and is a named agreement. The special provisions that apply are Law Number 36 of 2009 concerning health and other regulations related to the administration of stem cells in Indonesia.

In the agreement of the two parties, a patient's motivation to go to a doctor is nothing but asking for help so that the doctor can cure his illness. One of them is patients in medical services using stem cells. The patient comes to the doctor and explains his illness; then, the doctor will give directions for medical activities related to his desire to carry out treatment with stem cells. Before being applied to patients, the process of stem cell medical procedures will first undergo screening at a health clinic to find out precisely what disease the patient is suffering. After it was clear what disease, the patient was suffering from, whether the patient was worthy of using the stem cell method or simply using conventional treatment was analyzed. Before the doctor gives therapy to the patient, it must first be approved or agreed to take medical action; a medical agreement between a doctor and a patient is called informed consent [41].

Authority by the parties in medical services with stem cells is doctors and patients. The doctor has expertise and competence in stem cell medical services [38]. The patients are adults at least 18 years of age or married, healthy in mind, and not under guardianship as stipulated in Article 433 of the Civil Code. Expert doctors treat several diseases with stem cells at hospitals that the government has appointed, as stipulated in the Decree of the Minister of Health of the Republic of Indonesia Number 32 of 2014, concerning the Establishment of a Center for Development of Medical Services Research and Education of Tissue and Stem Cell Banks.

Particular objects and provisions regarding some issues related to legal objects (in this case, medical services) whose characteristics need to be emphasized. Medical agreements are the object of "healing efforts". In this case, the specific object is disease therapy with stem cells. Doctors should try their best to cure the patient's illness. Therefore, juridically, it generally belongs to the type of "*inspanning verbintenis*," i.e., doctors do not guarantee certainty in curing the disease. However, doctors are expected to assist in healing efforts with their efforts and expertise. The use of stem cells can only be done to cure disease and restore health and is prohibited from being used for reproductive purposes. According to Indonesian civil law, embryonic and non-embryonic stem cells are objects stored in stem cell banks. Therefore, stem cells can be categorized as "thing" because stem cells are deposited in a stem cell bank; these cells can be used as property rights. These stem cells are tangible objects because they are extracted stem cells. Stem cells are movable objects because they can be transferred from a stem cell bank to a hospital where the client or prospective recipient, in this case, the patient, will receive medical procedures using stem cells. Because of their transferable nature, stem cells are movable

objects, as stipulated in Article 509 of the Civil Code. However, stem cells cannot be the object of trade, but stem cells can be the object of a grant and a safekeeping agreement. Thus, stem cells fit the elements of objects as property rights listed in Article 570 of the Civil Code. Therefore, a therapeutic agreement model is needed that is able to accommodate the interests of the parties, not just an agreement that has economic or one-sided purposes.

For halal reasons, medical services with stem cells can only be performed to cure disease and restore health and are prohibited from being used for reproductive purposes [42]. This prohibition is stipulated in Article 64 in conjunction with Article 70 of Law Number 36 the Year 2009 concerning health and other implementing regulations. Furthermore, in Article 4, Regulation of the Minister of Health of the Republic of Indonesia Number 32 of 2018 concerning the Implementation of Stem Cell Services, it is determined that diseases that can be treated with stem cells include degenerative and non-degenerative diseases. Restoration of health includes the rejuvenation of cells, tissues, and organs. Prohibition for reproductive purposes prohibits using stem cells to create new individuals.

3.3. Legal policies of stem cell treatment and therapeutic contract model in several countries

Over the last decade, the use of human cell and tissue-based products in new and innovative therapies has drawn increasing interest from healthcare providers, researchers, patients, and regulators, internationally. However, despite few accepted clinical uses, stem cell treatments are increasingly being prescribed for conditions that have yet to be demonstrated as safe or effective in clinical trials.

Singapore does not have specific legislation to regulate stem cell treatment processes and products, although they broadly fall within the scope of The Medicines Act. Stem cells processed and stored for human transplantation in hospitals and medical clinics are covered under the Guidelines for Healthcare Institutions Providing Tissue Banking [43]. This guidance includes “all constituent parts of the human body, including surgical residues” but excludes solid organs, placenta, blood and blood products, and reproductive tissues, and does not include tissues that have been “processed in such a manner that their functional, structural and biological characteristics have been altered." These products are classified as biologics, which currently fall under the Medicines Act [44]. In Japan, under the pharmaceutical affairs law (PAL), the stem cell may be classified as ‘drugs’ if their action is pharmacological or ‘devices’ if their action is structural or physical. However, only those derived from processed human cells and tissues are regulated under the PAL. This includes stem cells that are expanded ex-vivo, treated pharmacologically for activation, biologically altered, combined with scaffolds, or genetically modified. By contrast, unprocessed stem cells are not regulated under the PAL [45]. Their use presumably falls within the practice of medicine, which is regulated by the medical practitioner law (MPL) (1948) [46]. The MPL, considers a practitioner's act of producing an unapproved drug and administering it to a patient as falling within the scope of 'physician discretion' in medical practice. Therefore, stem cells administered in this context are not governed by the PAL, and practitioners need not seek prior approval from the Ministry of Health, Labour, and Welfare when acting within this zone of discretion. Countries like Japan and Singapore are both seen as leaders in stem cell therapies and, though they might not have the outputs of China – are internationally recognized for the work they continue to do in the field. In Australia, stem cell treatment is regulated federally by the therapeutic goods administration (TGA) under the Therapeutic Goods Act (1989) according to a recently implemented framework for biologics [47]. Stem cells are collected from a patient under the clinical care and treatment of a registered medical practitioner and manufactured by that practitioner or under the professional supervision of that practitioner [48]. In this case, the stem cell must be used in treating a "single indication and in a single course of treatment of that patient by the same medical practitioner, or by a person or persons under the professional supervision of the same medical practitioner."

Legal policies by several countries indicate that stem cell treatment is influenced by the cultural and social positions concerning the legal and moral status of the human embryo. In this regard, we can argue that the fundamental basis for the stem cell treatment policies is hard to embedded not because it is influenced by aspects of sociocultural, economic, or political issues but the lack of stem cell knowledge, fear of knowledge misuse, and commercial exploitations of less privileged subjects and communities. Based on these international policies, it is evident that stem cell treatment or research is permissible in many countries and is independent of the sector affiliation as a barrier to a permissive stance as long as it utilizes the permissible sources, research purpose, and applications, and the necessary supervisory precautions to respect human life.

Therapeutic contract model, there are concerns regarding the lack of equality by the parties; in order to avoid the one-sided pursuit of a high contract rate-neglect the quality of contract services, the need for alternative solutions such as; based on existing contract services combined with the service capacity and resource allocation. All localities should shift work focus to improve quality and efficiency, place the quality of contracted services first, and continuously improve the patient's sense of fulfillment and satisfaction. The signing of the therapeutic contract is carried out in one assembly so that the rights and obligations of the parties (especially the patient) can be guaranteed from the start of the treatment procedure [49].

Policies should focus on improving the competence of health providers, incentivizing doctors to engage in patient-centered services, and encouraging more trustful and respectful patient-provider relationships to ensure the quality of health provider contract services [50]. In the "Three in one" contract model, competent and accountable health providers' attitude plays an important role because the health service was provided to contracted patients by a team consisting of specialists from hospitals, general practitioners, and health managers in community health service centers [51].

Guobao [51] and PeiPei [50] studies showed that with the “three in one” model of a medical (therapeutic) contract where health providers are willing to explain in detail related to patient rights, then the signing the doctor, patient and witness is carried out in one assembly [52]. As a result, health providers are more proactive in helping the patient, may accommodate the balance of rights and obligations of the parties, and have no one-sided pursuit of high contract rates that might affect the quality of contracts and patient care. This model of medical agreement has played a key role in treatment management, the influence of “three in one” model on the physiological indexes of patients has been examined. However, little attention has been paid to its effect on the health-related quality of life [53]. Unfortunately, these models currently need to be present in Indonesia because of the novelty of the regulatory framework and the custom

4. CONCLUSION

Efforts to treat disease using stem cells are allowed as long as they are carried out according to the national regulations. Several regulations have made it legal to treat disease with stem cells. The purpose of regulating the operation of stem cell is to provide legal certainty and protection to the public and administrators. The function of national regulation is related to using stem cells to ensure legal certainty and guarantee justice and benefit. When it comes to procedures and treatment using stem cells, only some can get services because the procedure starts with an inspection, collection and packaging, delivery to stem cell banks, blood tests, and processing of stem cells. The legal policy related to the role of hospitals as providers of stem cell treatment services in Japan and Australia shows the need for additional hospitals that provide stem cell services in Indonesia based on the Decree of the Minister of Health of the Republic of Indonesia Number 32/2014, because there are still many hospitals that have limited facilities, infrastructure, and human resources related to stem cell treatment.

Juridically, treating disease with stem cells is an example of a therapeutic contract. The legal subjects are doctors, patients, hospital, and health provider. Efforts to treat disease with stem cells in the perspective of civil law are categorized as an agreement to perform a particular service. The conditions for the validity of the Stem Cell Therapeutic Agreement are also determined based on the criteria provided by law in Article 1,320 of the Civil Code; namely, they agree that they are binding themselves, the parties' skills, a certain thing, and a lawful cause. The model of therapeutic contract that can maintain the honor of the parties is the "three in one." However, this model currently needs to be improved in Indonesia because of the novelty of the regulatory framework. Indonesia must regulate and require the parties (doctors, health providers, and patients) to declare their agreement in a therapeutic contract with a "three in one" model.

Legal policies by several countries indicate that stem cell treatment is influenced by the cultural and social positions concerning the legal and moral status of the human embryo. In this regard, we can argue that the fundamental basis for the stem cell treatment policies is hard to embedded not because it is influenced by aspects of sociocultural, economic, or political issues but the lack of stem cell knowledge, fear of knowledge misuse, and commercial exploitations of less privileged subjects and communities so it necessary for the government to make community understand regarding the existence of alternative treatments for degenerative and genetic diseases with stem cells.

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BIOGRAPHIES OF AUTHORS

Ahdiana Yuni Lestari is a lecturer and practitioner of health law at Universitas Muhammadiyah Yogyakarta. She can be contacted at email: Ahdianayunilestari@umy.ac.id.

Danang Wahyu Muhammad is an Associate Professor of the Post-Graduate Program and Faculty of Law at Universitas Muhammadiyah Yogyakarta, Indonesia. He can be contacted at email: Danangwahyu@umy.ac.id.

Izzy Al Kautsar is a Faculty of Law Universitas Sebelas Maret Indonesia student interested in legal, jurisprudence, social, and civil issues. He can be contacted at email: alkautsarizzy@gmail.com.

Siti Ismijati Jenie is a Full Professor of Civil Law at Universitas Gadjah Mada and a lecturer at Universitas Muhammadiyah Yogyakarta. She is also currently active as a speaker on public health issues. She can be contacted at email: Siti.Ismijati@umy.ac.id.