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Regulation of Stem Cell Transplantation: An Introduction to a Korean Court Decision

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Abstract

This article provides a general overview of the first Korean Supreme Court decision regarding stem cell transplantation. With the advancement of biotechnological research using different types of stem cells, in Korea, stem cell transplantation has been conducted on patients suffering from difficult to treat illnesses. However, since this treatment had not been subject to any specific Korean legislation, stem cell transplantation was beyond the reach of legal regulations. Under these circumstances, a group of patients who underwent stem cell transplantation filed a compensation suit against a doctor, a hospital, a corporation supplying stem cells, etc. In its decision 2007Da3162, the Korean Supreme Court for the first time officially set forth its position on stem cells, stem cell transplantation, and liability for damages related to stem cell transplantation. This article introduces the details of this court decision and considers the significance of this decision as a guideline for regulating stem cell transplantation.

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I. Stem Cell Transplantation in Korea

Ever since Woo-suk Hwang published in prestigious journals his success in creating human embryonic stem cells through cloning in 2004 and 2005, but was subsequently charged with embezzlement, etc. in 2006 after it was discovered that many parts of his research were fabricated, issues related to stem cell research have been widely discussed in Korea. At the early stage of stem cell research appearing in public discussion, ethical and legal issues of protecting human dignity and preventing harm to human beings were at the center. Since embryonic stem cells were mainly manipulated in this type of biotechnological research at that time, many expressed concern over infringement of human dignity while expecting a new possibility of curing diseases foreshadowed by this stem cell research.

During the development of stem cell research, induced pluripotent stem cells (commonly abbreviated as iPS cells) and adult stem cells (such as hematopoietic stem cells, mesenchymal stem cells, and neural stem cells), as well as embryonic stem cells, were widely employed. Almost simultaneous with the advancement of the stem cell research, stem cell transplantation was actually performed on patients whose diseases had progressed to a stage in which no other effective treatment method remained. However, because this new type of treatment had not been subject to any specific Korean legislation, stem cell transplantation

remained beyond the reach of legal regulations. In addition, as public attention on stem cells waned, the legitimacy of stem cell transplantation and the appropriate ways to regulate it have been discussed almost exclusively among professionals.

Under these circumstances, a group of patients who underwent stem cell transplantation claimed compensation damages against a doctor, a hospital, a corporation supplying stem cells, etc. In its decision 2007Da3162, the Korean Supreme Court officially put forth its position on stem cells, stem cell transplantation, and liability for damages related to stem cell transplantation for the first time. This article gives an overview of this court decision, which functions as a basis for regulating stem cell transplantation.

II. Supreme Court Decision 2007Da3162 Decided Oct. 14, 2010[1]

1. Facts

Seven patients filed a joint compensation suit against Halla Hospital, the director of Halla Hospital, Histostem, and the CEO of Histostem (hereinafter "the defendant et al."). Plaintiffs 1, 2, 3, 4, 5, and 7 and deceased non-party 1 (hereinafter "plaintiff 1 et al.") were patients suffering from liver cirrhosis at a stage significantly advanced wherein life expectancy ranged from six months to five years, and for whom current medical standards offered no effective treatment method besides liver

1. The Internet website of the Supreme Court Library of Korea provides an English translation of important Supreme Court Decisions (http://library.scourt.go.kr/). This article follows that translation, but edits the text of the original decision and gives supplementary information in the interests of clarity.

transplant surgery. Plaintiff 6 (hereinafter "the plaintiff et al." collectively with plaintiff 1 et al.) was diagnosed with multiple sclerosis (a disease where spinal damage causes defects in neural tissue, resulting in paralysis in the nerves of the leg and impairment in urination and bowel movements), for which no effective treatment method is available under current medical practice.

Defendant 2, director of Halla Hospital, performed a procedure injecting cord blood stem cells supplied by the defendant corporation Histostem (hereinafter the "defendant corporation") into the abdominal region of non-party 2 (female, 45 years old at the time), a patient suffering from liver cirrhosis on Sep. 3, 2003, and on non-party 3 (male, 58 years old at the time), a patient suffering from the same symptoms, on Oct. 8, 2003.

On Nov. 4, 2003, defendant 2 held a joint press conference together with defendant 4, the CEO of the defendant corporation, where they announced that they had "transplanted cord blood stem cells into two liver cirrhosis patients and obtained significant improvement in liver function as a result." The defendant medical corporation in operation of Halla Hospital, Halla Medical Foundation (hereinafter the "defendant medical corporation"), announced through the Halla Hospital homepage that "Korea has succeeded in the word's first clinical trials for treatment of liver cirrhosis using stem cells separated from umbilical cord blood," that "various tests on the patients receiving the procedure show significant improvement in liver function, with non-party 2 in particular showing rapid improvement to full recovery after being diagnosed with late-stage liver cirrhosis, and is now well enough to climb Halla mountain," and that "this success proves the efficacy of stem cells."

The defendant corporation also posted statements on the Internet homepage of the Seoul Cord Bank, announcing their "success in clinical trials to treat liver cirrhosis, etc. by applying stem cells extracted from

umbilical cord blood," and that "liver cirrhosis, hair loss, spinal damage, avascular osteonecrosis, Buerger's disease can be treated with cord blood stem cells, while other conditions such as Alzheimer's disease, diabetes, cardiac disease, stroke, muscular dystrophy, Parkinson's disease, malignant lymphoma show the possibility of treatment with cord blood stem cells." These announcements introduced defendant 2 as the director of Halla Hospital, a facility affiliated with the Seoul Cord Bank, and quoted defendant 2 as saying, "these results will be recorded as the world's first [successful] cases."

The press conference and Internet announcements received wide media coverage on Nov. 4, 2003, through several channels reporting that "clinical trials of a technique to treat liver cirrhosis by transplanting stem cells from umbilical cord blood have succeeded." However, the two patients for whom clinical trials had been reported to have succeeded had actually shown but a single change in some test measurements of their liver function, at a level insufficient to firmly establish clinical treatment effect. Non-party 2 continued to show progression in liver cirrhosis and eventually passed away in May of 2004, approximately nine months after receiving stem cell transplantation.

Plaintiff 1 et al. consulted with Halla Hospital, concentrating their inquiries on the treatment effect of stem cell transplantation. Defendant 2 and non-party 4, the nurse in charge of stem cell treatment, informed plaintiff 1 et al. that they could not present statistics about treatment effect, and failed to inform them that non-party 2 had not actually climbed Halla mountain or regained health to the extent that she would be able to. Furthermore, they emphasized the merits of the transplantation of this case, claiming that the procedure was superior to the current treatment method of liver transplant surgery when considering surgical method, cost, side-effects, and treatment effect, etc. During the process of

purchasing stem cells from the defendant corporation, through introduction by defendant 2, plaintiff 1 et al. made concerned inquires about the treatment effect of the procedure to non-party 5, an employee at the defendant corporation who processed their purchase contract, to which non-party 5 stated he had witnessed an acquaintance of his recover from diabetes symptoms and also regain hair as well.

Plaintiff 6 read the above media reports and purchased stem cells through consultation with defendant 4. Following this, plaintiff 6 was referred to Halla Hospital by defendant 4 and received the above explanation provided to plaintiff 1 et al. by defendant 2, etc.

From Dec. 2003 to Mar. 2004, the plaintiff et al. was hospitalized at Halla Hospital for several days each to receive the stem cell transplantation of this case. While their existing conditions did not worsen nor any side-effects occur after the procedure, neither did their existing conditions improve nor disease progression slow down. Plaintiff 1 et al. each spent ₩30,000,000 to ₩33,000,000 per person to purchase stem cells, while plaintiff 6 spent ₩20,000,000 toward this purpose. The plaintiff et al. each spent around ₩2,000,000 to ₩3,000,000 per person on treatment costs.

2. Progress of the Case

The plaintiff et al. listed the following issues in their complaint and demanded compensation for damages from the defendant et al. by contending that the defendant et al.'s acts established the liability of joint tortfeasors. (1) The defendant et al. deceived the plaintiff et al., by holding the joint press conference together and posting false and exaggerated advertisements on the homepages of Halla Hospital and the defendant corporation concerning the effect of the stem cell transplantation. This joint

deception resulted in the stem cell transplantation contracts between the plaintiff et al. and the defendant et al. (2) Even though the mesenchymal stem cells of this case fell under a drug as defined by the previous Pharmaceutical Affairs Act, the defendant et al. conducted the stem cell transplantation of this case without obtaining approval of a clinical trial from the Commissioner of the Korea Food and Drug Administration. (3) The defendant et al. conducted the stem cell transplantation of this case without providing information or explanation of the safety and validity (treatment effect) of the medical treatment prior to conducting the transplantation. As such, the defendant et al. committed a clinical trial under the disguise of treatment, which deprived the plaintiff et al. of the opportunity of receiving appropriate treatment in due course, as well as invading the plaintiff et al.'s personal rights and human dignity.

Responding to the plaintiff et al.'s complaint, the defendant et al. refuted the plaintiff et al.'s claims, as follows, and argued their lack of liability for damages compensation. (1) Even if the defendant et al. admitted that the effect of the transplantation was posted on the Internet homepages or reported in the broadcast media in a somewhat exaggerated manner, the defendant et al. did not deceive the plaintiff at al. by falsely exaggerating the effect of the stem cell transplantation of this case. (2) Since the mesenchymal stem cells of this case were transplanted after cultivating a small amount of hematopoetic stem cells without going through any out-of-body process, the mesenchymal stem cells did not fall under the definition of a drug. Therefore, the defendant et al. was not required to obtain approval of a clinical trial prior to conducting the stem cell transplantation of this case. (3) The defendant et al. performed their duty to explain to patients, by informing the plaintiff et al. the side-effects of the stem cell transplantation—such as bleeding, infection, and hemorrhagic shock—and the present status of no existing statistics

regarding the effects of the transplantation. In addition, even if the defendant et al. violated their duty of explanation, there was no causal relationship between this violation and the plaintiff et al.'s damages, because the plaintiff et al. decided to undergo the stem cell transplantation of this case in a state in which no other effective treatment methods were available.

The Seoul Eastern District Court decided partially in favor of the plaintiff et al.,[2] and both the plaintiff et al. and the defendant et al. appealed to the Seoul High Court. The Seoul High Court accepted the plaintiff et al.'s claims (2) and (3) and admitted the defendant et al.'s liability of compensating the plaintiff et al.'s damages as joint tortfeasors. However, the Seoul High Court limited the scope of the defendant et al.'s liability considering the defendant et al.'s lack of recognition of their violation of the previous Pharmaceutical Affairs Act, no significant deterioration occurred to the plaintiff et al. after the stem cell transplantation, the nature of the treatment in this case as a minor operation which required only local anesthesia and was completed within a half to one hour, etc.[3] Against this court decision, the defendant et al. and plaintiff 6 filed an appeal to the Supreme Court of Korea. The defendant at al. raised objections to the Seoul High Court's judgment on the establishment of torts and range of compensation for damages, while plaintiff 6 disputed the limitation of defendant et al.'s liability.

3. Findings

The Supreme Court of Korea dismissed all appeals. In its decision, the

2. Seoul Eastern District Court Decision 2004Gahap8263, Dec. 1, 2005.

3. Seoul High Court Decision 2006Na15474, Dec. 14, 2006.

Supreme Court examined the following five main issues in great detail.

(1) Issue 1: Whether the mesenchymal stem cells of this case are drugs as defined under the Pharmaceutical Affairs Act

The previous Pharmaceutical Affairs Act (wholly amended by Act No. 8365 of Apr. 11, 2007, hereinafter the "Pharmaceutical Affairs Act") provides a definition of drugs (Article 2 (4)),[4] and stipulates that a person who intends to make a business of manufacturing drugs must obtain permission from the Commissioner of the Korea Food and Drug Administration as prescribed by Ordinance of the Ministry of Health and Welfare (Article 26),[5] and that any person who intends to conduct a

4. **Article 2 of the previous Pharmaceutical Affairs Act (Definitions)** For the purpose of this Act, the definitions of terms used in this Act shall be as follows: (4) The term "drug" means an article falling under any of the following items: 2. Articles used for the purpose of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery or equipment.

5. **Article 26 of the previous Pharmaceutical Affairs Act (Permission of Manufacturing Business, etc.)** (1) A person who intends to make a business of manufacturing drugs shall obtain permission from the Commissioner of the Korea Food and Drug Administration as prescribed by Ordinance of the Ministry for Health, Welfare and Family Affairs after being equipped with necessary facilities pursuant to the standards for the facilities prescribed by Presidential Decree. (2) A person who intends to make a business of manufacture of products other than drugs shall make report of a manufacture business to the Commissioner of the Korea Food and Drug Administration after being equipped with necessary facilities pursuant to the standards for the facilities prescribed by Presidential Decree and obtain permission for items by item or make report on items. (3) Deleted. (4) A person who has obtained permission for items or has made report on items pursuant to paragraphs (2) and (3) may set up a business office as prescribed by Ordinance of the Ministry for Health, Welfare and Family Affairs. (5) A person who falls under any of the following subparagraphs shall not obtain permission or shall not make report of a manufacture business or a manufacture by entrustment and sale business of drugs or products other than drugs (hereinafter referred to as "drugs"): 1. A person falling

clinical trial using drugs, etc. must work out a clinical demonstration plan and obtain approval thereof from the Commissioner of the Korea Food and Drug Administration (Article 26-4 (1)).[6] The previous Enforcement Rule of the Pharmaceutical Affairs Act (amended by Ordinance of the Ministry of Health and Welfare No. 291 of Jul. 28, 2004) states that drugs approved for use in clinical trials are not allowed as subject of manufacture or item permission (Article 21-2).[7]

As such, while the Pharmaceutical Affairs Act grants to the Commissioner of the Korea Food and Drug Administration the authority to approve clinical demonstration plans or permit items for manufacture,

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under any of subparagraphs of Article 4 (1); 2. A person in whose case one year has not passed since the revocation of permission of a manufacture business or closing of an office of a manufacture by entrustment and sale business or a factory pursuant to Article 69. (6) In case of paragraph (1), if an item permission of which is intended to be obtained is a new drug or a drug designated by the Commissioner of the Korea Food and Agriculture Administration, test results and documents related to the safety and effectiveness, and other necessary data shall be submitted as prescribed by Ordinance of the Ministry for Health, Welfare and Family Affairs. (7) Deleted. (8) When obtaining permission of or making report on a manufacture business, a manufacture by entrustment and sale business and items of manufacture and sale of drugs, etc. under paragraphs (1) through (4) and (7), matters necessary for the objects, standards, conditions, management, etc. of permission or report shall be prescribed by Ordinance of the Ministry of Health, Welfare and Family Affairs. (9) Deleted.

6. **Article 26-4 of the previous Pharmaceutical Affairs Act (Approval of Clinical Demonstration Plan, etc.)** (1) Any person who intends to conduct a clinical demonstration using drugs, etc. shall work out a clinical demonstration plan and obtain approval therefor from the Commissioner of the Korea Food and Drug Administration. The same shall apply to a case where he/she intends to alter the approved clinical demonstration plan.

7. **Article 21-2 of the previous Enforcement Decree of the Pharmaceutical Affairs Act** Drugs, etc. falling under any of the following subparagraphs shall not be allowed as subject for manufacture business or item permission under Article 26 (1) of the Act. 1. Clinical trial drugs, etc. approved for use in clinical demonstration plans under Article 28 (1).

it does not delegate the authority to define the specific scope of drugs to lower statutes. Thus, whether a drug is subject to the Pharmaceutical Affairs Act must be determined through interpretation of definitions provided in Article 2 of the Act. Article 2 (4) 2 of the Pharmaceutical Affairs Act includes "articles used for the purpose of diagnosis, medical care, alleviation, treatment or prevention of diseases of human beings or animals, excluding appliances, machinery or equipment" within the scope of drugs. Accordingly, when a cell is isolated from a human body and used in a unit of cells, not as human tissue, for the purpose of treating human diseases, this falls under a drug as defined by the above provision and becomes subject to regulation under the Pharmaceutical Affairs Act.

[T]he mesenchymal stem cells of this case (hereinafter the "stem cells of this case") are selected from white blood cells in cord blood stored at a low temperature, separated from hematopoetic stem cells, etc., and proliferated and cultivated out of the body by adding growth factors, etc., after which they are injected into a person's body in a unit of cells for the purpose of treating human diseases. Therefore, the stem cells of this case must be seen as a drug subject to regulation under the Pharmaceutical Affairs Act.

(2) Issue 2: Whether the stem cell transplantation of this case constitutes a clinical trial under the Pharmaceutical Affairs Act

Article 26-4 (1) of the Pharmaceutical Affairs Act stipulates that a person who intends to conduct a clinical trial using drugs, etc. must work out a clinical demonstration plan and obtain approval therefor from the Commissioner of the Korea Food and Drug Administration. Within this context, a clinical trial is a study performed upon human subjects for which the safety and validity has not been sufficiently verified through

knowledge and experience up to the time of the study.

[T]he stem cell transplantation of this case was a procedure for which the safety and validity had not been sufficiently verified through knowledge and experience up to the time of being performed, thus making it a clinical trial. Therefore, the act of transplanting the stem cells of this case without obtaining permission from the Commissioner of the Korea Food and Drug Administration is a violation of the Pharmaceutical Affairs Act, regardless of the fact that guidelines exist to assess medical insurance cost related to transplantation of hematopoietic stem cells, which are similar to the stem cells of this case. Accordingly, the [Seoul High Court] was just to rule the act of transplanting the stem cells of this case without permission from the Commissioner of the Korea Food and Drug administration a violation of the Pharmaceutical Affairs Act.

(3) Issue 3: Whether the unapproved clinical trial of this case by itself establishes tort liability

Even when a medical act falling under the category of clinical trial has been performed without permission in violation of relevant statutes prescribing approval from a supervising government office, this itself does not constitute a violation of the medical duty of care. Accordingly, when no specific violation of the medical duty of care can be acknowledged for the medical act in question, tort liability does not arise from this act itself (see Supreme Court Decision 2001Da27449, Jan. 11, 2001).

Therefore, the [Seoul High Court] was wrong to rule that the act of transplanting the stem cells of this case, which are drugs, without receiving approval from the Commissioner of the Korea Food and Drug Administration constitutes a tort in itself. However, as will be explained [in Issue 4], tort liability can be acknowledged for the defendants from

violation of their duty to explain, thus meaning that the above error did not affect the conclusion of the [Seoul High Court's] decision.

(4) Issue 4: Whether the public statements etc. of the doctor, medical corporation, etc. of this case constitute a violation of the duty to explain

A doctor has the duty to explain to the patient, or his/her legal representative, such information as symptoms of the illness, contents and necessity of treatment methods, foreseeable dangers, etc., which can be acknowledged as being appropriate in light of current medical standards, and thus allow the patient to choose whether to receive the medical act after sufficient comparison of the need and dangers involved (see Supreme Court Decision 94Da3421, Jan. 20, 1995). In particular, when these medical acts take place at the clinical trial stage, the safety and validity (treatment effect) of the medical act in question must be explained in comparison with general and standard medical acts being performed clinically at the time. [W]hen supplying drugs at the stage of clinical trial the supplier is obligated under the principle of good faith to inform the consumer about important circumstances such as the safety and validity (treatment effect) of the drug in question, which can affect his/her decision to purchase the drug (see Supreme Court Decisions 93Da62645, Mar. 28, 1995; 2005Da5812, 5829, 5836, Jun. 1, 2007). Meanwhile, in cases of several persons jointly inflicting damage on another person, Article 760 of the Civil Act provides that objective demonstration of the joint relevance of their joint acts is sufficient to establish the liability of joint tortfeasors who have caused damage (see Supreme Court Decision 2002Da35850, Jan. 10, 2003).[8]

8. **Article 750 of the Civil Act (Definition of Torts)** Any person who causes losses to or inflicts injuries on another person by an unlawful act, willfully or negligently, shall be bound to make compensation for damages arising therefrom. **Article 760 of the**

[According to the established facts,] defendant 2 violated the duty of explanation toward patients by providing them with false information via the joint press conference with defendant 4, advertisements on the Halla Hopsital homepage, consultation sessions, etc., without making an effort to objectively confirm the treatment effect of the stem cell transplantation of this case at the clinical trial stage, when this would have served as important information for the patients to base their decision on. Defendant 4 also violated the duty of explanation, as well as the duty of notification, toward stem cell consumers by providing these consumers with false information via the joint press conference with defendant 2, advertisements on the Seoul Cord Bank homepage, consultation sessions, etc., without making an effort to objectively confirm the treatment effect of the stem cell transplantation of this case at the clinical trial stage, when this would have served as important information for consumers to base their decision on. In light of the details of the above press conference, the relevance of the homepage material, and the details of how the patients purchased stem cells and received transplants, etc., the objective joint relevance of the torts committed by defendant 4 and defendant 2 establish them as joint tortfeasors.

In addition, the CEO of a corporation is jointly and severally liable, together with the corporation, to make compensation for any damage inflicted on another person during the course of conducting business (see Article 389 (3), Article 210 of the Commercial Act). While the defendant company assumes responsibility for its torts, this does not absolve the individual responsibility of defendant 4 as CEO.

Civil Act (Liability of Joint Tortfeasors) (1) If two or more persons have by their joint unlawful acts caused damages to another, they shall be jointly and severally liable to make compensation for such damages. (2) The provisions of paragraph (1) shall also apply if it is impossible to ascertain which of the participants, albeit not joint, has caused the damages. (3) Instigators and accessories shall be deemed to act jointly.

(5) Issue 5: Whether the legal principles regarding the scope of liability for damages compensation are justly applied in this case

If defendant 2, etc. did not provide false information about the treatment effect of the stem cell transplantation of this case, the plaintiff et al. would not have paid such large amounts of money to purchase the stem cells of this case at the stage of clinical trial and receive transplant procedures. Therefore, the [Seoul High Court] was just to rule that a causal relation exists between the property loss sustained by the plaintiff et al., through the purchase of stem cells and treatment, etc., and the joint torts committed by defendant 2, etc.

When a doctor, etc. is found liable for damage caused to a patient through negligent treatment or violation of the duty of explanation, the scope of damages compensation must be defined by considering such circumstances as the content and extent of negligence on the part of the doctor, the details and difficulty of the treatment, the result of the medical act, characteristics of the disease in question, and the physical constitution and conduct of the patient, after which a limit can be placed on the amount of damage compensation assessed in light of the principle of equity in sharing loss (*see* Supreme Court Decision 98Da12270, Jul. 24, 1998). Except for cases where this is found to be significantly unreasonable in light of the principle of equity, proceedings at the trial court hold full authority for all fact-findings or ratio determinations for mitigation of liability (*see* Supreme Court Decision 2006Da19603, Nov. 30, 2007). Reviewing the reasoning of the [Seoul High Court's] judgment ⋯ in light of the above legal principles shows there are no grounds to view determinations made by the [Seoul High Court], about fact-findings regarding grounds to mitigate liability or about the ratio to which liability is mitigated, as being significantly unreasonable in light of the principle of equity.

III. Significance of the Supreme Court Decision

As the first decision concerning the liability for damages related to stem cell transplantation, the Korean Supreme Court's 2007Da3162 Decision indicates its stance of including stem cells into the category of drugs regulated by the Pharmaceutical Affairs Act. Therefore, it becomes clear that stem cell transplantation is an act of injecting a drug directly into a patient's body, which requires approval from the Commissioner of the Korea Food and Drug Administration.

The Supreme Court, however, explicitly rules that an unapproved clinical trial, violating the Pharmaceutical Affairs Act, itself does not constitute a violation of the medical duty of care. According to the Supreme Court's reasoning, only when a doctor's specific violation of the medical duty of care is admitted is the doctor liable for a patient's damages. On the other hand, the Supreme Court specifies a list of matters that a doctor and a supplier of a drug should explain to a patient or his/her legal representative, especially when the medical acts take place at the clinical trial stage. Alleviating the patient's burden of proving the lack of effectiveness of stem cell transplantation, the Supreme Court determines that the violation of this duty of explanation incurs tort liability of a doctor and a supplier of a drug at a clinical trial. Furthermore, the Supreme Court admits the liability of joint tortfeasors between a doctor and a representative of a drug supplying corporation when they held a joint press conference and advertised the effects of the treatment together, but neglected to provide sufficient information about stem cell transplantation.

In conclusion, this Supreme Court Decision offers a new direction in enhancing the safety and validity of stem cell transplantation and respecting rights of human beings in clinical trials. The significance of this

decision lies in its ensuring the application of a rigorous safety and validity assessment procedure to stem cell transplantation and clarifying the patient's right to an explanation from his/her doctor and from the supplier of a drug at a clinical trial.

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