International Journal of Medical Toxicology & Legal Medicine Volume 27, No. 1s, 2024
e-ISSN: 0974-4614
p-ISSN: 0972-0448

Article Submitted: 10-05-2024; Revised: 20-06-2024; Accepted: 18-07-2024

Unveiling the Regulatory Landscape of Stem Cells in India: Assessing Challenges and Opportunities

[1]Ms. Rahi Samuel Alhat, [2]Dr. Sukhvinder Singh Dari
[1]Ph.D Reseach Scholar,
Symbiosis International (Deemed University), Pune.
[2]Professor, Symbiosis Law School, Nagpur,
Symbiosis International (Deemed University), Pune.

Abstract:

The significance of stem cell technology continued in the Indian medical field with the release of the 2019 revised national guidelines on stem cell research. Strict guidelines were enforced by the Department of Biotechnology (DBT) and the Indian Council of Medical Research (ICMR), mandating that stem cell therapy be carried out within the parameters of clinical trials. The ethical and legal implications of stem cell research persisted, particularly in relation to the killing of human embryos in order to harvest embryonic stem cells for study and medical use. Religions from Judaism and Islam support this ethical argument, whereas Buddhism and Hinduism are against it. The ethical standing of embryos and the legal framework controlling stem cell research in India are examined in this article.

Key Words:- Stem Cells, Embryonic Stem Cells, Regulations, Therapeutic Use, Self Renewal and Specializes Cells.

Introduction:

In 2019, the Indian medical sector witnessed significant advancements and discussions surrounding stem cell research following the release of updated national guidelines. Stem cell technology has remained a focal point, with the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) continuing to enforce strict regulations. These regulatory bodies have mandated that stem cell therapy be conducted under the clinical trial framework, ensuring rigorous oversight and adherence to ethical standards. This ongoing regulation reflects the commitment of Indian authorities to balance scientific innovation with ethical considerations.

Stem cell research, while promising, is not without its controversies, particularly concerning the ethical implications of using embryonic stem cells. The destruction of human embryos for the purpose of extracting these cells has sparked a complex debate deeply rooted in ethical, religious, and legal dimensions. Religious texts and teachings from various traditions offer differing views on this issue. For instance, Judaism and Islam provide specific justifications for the practice, whereas Hinduism and Buddhism generally oppose it. This article delves into the moral status of embryos and explores the mechanisms in place for regulating stem cell research in India, highlighting the multifaceted nature of this ongoing debate.

What Are Stem Cells?

A primitive cell can either self-renew (reproduce itself) or give rise to more specialized cell types. Stem cells act as an internal repair system that has the potential to develop into different cell types in the body. Cells are eternal elements of the human body. The human body is a large group of cells capable of functioning correctly. Stem cells are the initial cells that can develop into more specialized cells such as muscle cells, red blood cells, white blood cells, brain cells, etc. When stem cells divide, they either remain as stem cells or become another type of cell.

Stem cells are distinguished from other cell types by two essential characteristics. First, they are unspecialized cells capable of renewing themselves through cell division, sometimes after long periods of inactivity. Second, under certain physiologic

or experimental conditions, they can be induced to become tissue or organ-specific cells with unique functions. In some organs, such as the gut and bone marrow, stem cells regularly divide to repair and replace worn-out or damaged tissues. In other organs, however, such as the pancreas and the heart, stem cells only divide under particular conditions. Stem cells are essential for living organisms for many reasons. In the 3 to 5-day-old embryo, called a blastocyst, the inner cells give rise to the entire body of the organism, including all of the many specialized cell types and organs such as the heart, lung, skin, sperm, eggs and other tissues. In some adult tissues, such as bone marrow, muscle, and brain, discrete populations of adult stem cells generate replacements for cells that are lost through normal wear and tear, injury, or disease.[1]

Stem cells are classified as embryonic stem cells, adult stem cells and induced pluripotent stem cells. Embryonic stem cells are derived from the inner mass of the blastocyst, having the potential to self-renew and pluripotent (Pluripotent stem cells can give rise to all types of adult tissue cells plus extra-embryonic tissue, i.e. cells that support embryonic development) in nature. The controversy of stem cells revolves around embryonic stem cells, where as soon as the stem cells are extracted from the inner mass of the blastocyst, the embryo gets destructed here; ethical restraint comes into the picture, which argues that it is unethical to destroy the potential life (which exist in an embryo) for alleviating the sufferer.

In this debate, there are two views in place: first is that the use of human embryos for deriving embryonic stem cells is exceptionally unethical as it has an impact of instrumentalization of the human body. Second, the use of human embryos for deriving embryonic stem cells is not unethical, provided the strict safeguards have been duly met. This debate about embryonic stem cells brought stem cell technology into the limelight. Adult stem cells are cells found in organs or differentiated tissue having limited capacity for self-renewal and differentiation. These cells can differentiate into the cell types of which they are part; for example, the liver cells shall differentiate into liver cells and not RBCs. Induced pluripotent stem cells are adult cells that are engineered in such a way that such cells start behaving as embryonic stem cells and start differentiating into any cell type. The avenue of induced pluripotent stem cells is new, and research is being done in this field as it is an excellent alternative to embryonic stem cells.

Religious Views On Stem Cells:-

The debate of stem cells mainly revolves around the moral status of an embryo where an embryo is destroyed to derive the embryonic stem cells. Religious texts such as Judaism, Hinduism, Buddhism, and Islam have expressly talked about the moral status of embryos in the therapeutic use of stem cells. **Judaism** emphasizes its aim of saving life and hence allows the use of embryos for therapeutic use, where the ultimate goal of embryonic stem cell therapy is to cure the sufferer. Judaism doesn't grant human status to human fetuses less than 40 days old or preimplantation embryos. According to the **Islam**ic faith, the soul starts breathing in an embryo only after the 40^{th} day of fertilization and hence does not accord the legal status to an embryo until the 40^{th} day of fertilization and permits the therapeutic use of the embryo for stem cell research and therapy. **Hinduism and Buddhism** are considered strict religions as far as the moral status of embryos is concerned and do not permit the use of embryos for therapeutic use. **Roman Catholic, orthodox, and conservative protestant churches** accord the status of a human person to an embryo from the date of fertilization of the egg. In contrast, **less conservative protestant churches** permit the research of a human embryo before the 14^{th} day of fertilization.

This brief overview of religious views on stem cells points out the contrast among the religions on the moral status of embryos. In a country like India, where religion and caste play an essential role even in the election of president, the contrast of religious views on the status of embryos is confusing.

Unborn Child, Potential Life And Embryo- Conflicting Statutory Overview

Indian legal system conceptualized unborn child and its rights in various statutes, and said provisions of the statutes helped the researcher to interpret and differentiate between the conflict of the term unborn child and potential life in the foetus. Article 21 of the Indian Constitution grants and upholds fundamental rights to any person, including an unborn child as well. Apart from the Indian Constitution, various legislations such as Section 316, read with Section 316 of the Indian Penal Code, punishes a person for the death of an unborn child, Section 416 of Code of Criminal Procedure, 1973 provides postponement or reduction of capital punishment of pregnant women with the object of saving to potential life in the foetus and Section 13 read with Section 20 of Transfer of Property Act, 1882 deals with the transfer for the benefit of unborn

person. The abovementioned provisions of law recognize the concept of unborn child, but nowhere defines the word unborn child. Hence, here, it can be very well concluded that the legal status of unborn children in India is confusing. Judgments of the Indian court ease the interpretation of the word unborn child.
Judiciary cautiously interpreted the concept of an unborn child in its judgment Divisional controller, BTS Division, Karnataka State Road Transport Corporation V. Vidya Shinde[2] foetus which has completed 37 weeks for all the purposes be considered as a child even though it is a stillborn child. In Oriental Insurance Co. Ltd v. Santhilal Patal[3] , an Unborn child aged five months onwards in the mother's womb till its birth can be treated as a child in existence. Technically, the term developing ovum is used for the first seven to ten days after conception. It is called an embryo from one week to the end of the second month, and later, it is called a foetus. It becomes an infant only when it is ultimately born. The court believed that the concept of an unborn child and its rights and duties would come into force only after seven months of pregnancy, as in many instances, premature delivery takes place during the seventh month of pregnancy, and the child still survives. Hence, an unborn child aged five months onwards in the mother's womb till its birth can be treated as equal to a child in existence. The unborn child to whom live birth never comes can be held to be the person who can be subject to an action for damages for his death.

In Prakash and Another v. Arun Kumar Saini, another[4] unborn child aged five months onwards in the mother's womb till its birth can be treated as equal to a child in existence. The unborn child to whom live birth never comes can be held to be the person who can be subject to an action for damages for his death. The foetus is another life in women, and the loss of the foetus is actually a loss of a child in the offing.

On the perusal of the abovementioned judgments, it can be concluded that a foetus of 5 months and onwards can be termed an unborn child. Hence, it can be very well concluded that the destruction of the foetus for the therapeutic use of stem cells before its 5th month could not be construed as culpable homicide of potential life as courts have specifically differentiated between unborn child potential child and embryo. Judgments make it clear that women do not carry potential life till the completion of 5 weeks of pregnancy, which, on the contrary, suggests that from conception till the expiry of 5 weeks of pregnancy, the embryo does not carry life within and which makes it permissible to support research in the field of embryonic stem cells for the therapeutic use. The judgments of the courts overrule the intentions of the framers of the guidelines of 2007, 2013 and 2017 and alternatively permit embryonic stem cell research to some extent as it can't be considered as the homicide of potential life. The analysis of the judicial position and legislative intent behind framing guidelines banning stem cell therapy depicts the lack of coordination among the three pillars of Indian Democracy.

Global Stance On Stem Cell Regulation

Australia:

The laws in Australia relating to human embryonic stem cell research have undergone significant changes over the past decade. In 2002, the Australian Parliament passed the Prohibition of Human Cloning for Reproduction Act, which banned all kinds of human cloning, regardless of the purpose, and also banned all *in vitro* conception for purposes other than "achiev[ing] pregnancy in a particular woman."[5]Parliament also passed the Research Involving Human Embryos Act, which allowed for research on "excess ART embryos" if licensed by the National Health and Medical Research Council (NHMRC).

The cloning ban was loosened with the passage in 2006 of the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act.[6] The Act retained the ban on so-called reproductive cloning, but it allowed SCNT for research purposes, so long as the cloned embryo did not grow beyond fourteen days.[7]Such research is

permitted pursuant to the issuance of licenses by the NHMRC.[8]Human-animal hybrid embryos are permitted under the same licensing and similar growth restrictions, while the creation of chimeric embryos is altogether prohibited. (A "hybrid," in Australian law, is an embryo created by combining gametes or genetic material from two different species. A chimeric embryo is "a human embryo into which a cell, or any part of a cell, of an animal has been introduced.")

European Union:

Since 1984, the European Union has provided funding for scientific research through a series of "framework programs for research and technological development."[9]From 2002 to 2006, under the Sixth Framework Program, the E.U. provided funding for research using embryonic stem cells, although it did not finance the actual Act of destroying the embryos to derive the stem cells. In 2006, ministers of Science from the E.U. met to discuss the funding policies for the Seventh Framework Program and upheld their previous stance.[10] Also funded as part of the Sixth Framework Program was a human E.S. cell registry, which began operations in April 2007 in order to make efficient use of pre-existing E.S. cell lines.[11]More recently, a legal battle over whether stem cell techniques can be patented may alter the research landscape, as the removal of the legal protections provided by the patent system might significantly dampen incentives for stem cell research in the E.U.[12]

South Korea:

The South Korean legislation on human E.S. cell research is the Bioethics and Safety Act, which came into effect on December 6, 2008.[13]The Act prohibits human reproductive cloning and prohibits the production of embryos for non-reproductive purposes. Nonetheless, sources of human E.S. cells permitted under the Act include SCNT "for the purpose of conducting research aimed at curing rare or currently incurable diseases" and "spare" IVF embryos if they have exceeded a maximum storage period of five years or if researchers receive consent from their parents. Payment for gametes is prohibited as well, although oocyte donors may be reimbursed for costs associated with the procedure.

The 2008 law replaces the Bioethics and Biosafety Act of 2005,[14] which had been criticized for failing to protect not only human embryos but embryo and egg donors as well. The 2005 law was repealed in large part due to the scandals surrounding South Korean researcher Hwang Woo Suk. In papers published in *Science* in 2004 and 2005, Hwang claimed to have successfully cloned human embryos and derived stem cells from them. These claims made him a national hero — until it was revealed early in 2006 that his results were fabricated and that he had pressured his female subordinates to donate oocytes for his research. Hwang's high-profile fraud and brazen ethical lapses, which had slipped through the cracks of South Korea's biotechnology policy regime and caused a national embarrassment, prompted the 2008 legislation.[15]

United Kingdom:-

The U.K. has liberal regulations for human E.S. cell research. Permitted sources of E.S. cell lines under the 2008 Human Fertilization and Embryology Act (HFE Act) include unused IVF embryos, embryos created by IVF specifically for research purposes, embryos created by SCNT, "admixed embryos" including hybrids (created from human and animal gametes), "cytoplasmic hybrids" (created by SCNT using human nuclei and animal oocytes), transgenic human embryos (created by introducing animal DNA into a human cell), chimeric human embryos (created by introducing one or more

animal cells into a human embryo), or any other embryos that contain both human and animal DNA, but in which animal DNA is not predominant.[16]Research on embryos that are over fourteen days old is prohibited.[17]

The Human Fertilization and Embryology Authority (HFEA) is responsible for enforcing the regulations of the HFE Act and for licensing both IVF clinics and scientists researching human embryos. The HFEA will not grant a license for embryo research unless it is satisfied that the use of embryos is necessary for the research and that the research is relevant to the purposes specified by the HFE Act; these purposes include increasing knowledge about severe medical conditions, developing treatments for serious medical conditions, advancing the treatment of infertility, increasing knowledge about the causes of miscarriage, developing more effective contraception techniques, developing methods for detecting genetic or mitochondrial abnormalities in preimplantation embryos, and increasing knowledge of embryonic development.

In addition, the HFEA requires licensees to deposit a sample of the cell lines they generate in the U.K. Stem Cell Bank. Licensees must have approval from the Steering Committee for the U.K. Stem Cell Bank before conducting secondary research projects on human E.S. cells.

United Nations:

While the U.N. does not have a policy on human embryonic stem cell research *per se*, on March 8, 2005, the General Assembly approved a non-binding Declaration on Human Cloning, which called on member states "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."[18]However, the official press release announcing the vote describes the Declaration as "a weak, non-binding political statement" that does not "reflect anything approaching consensus within the Assembly" and thus does not affect the stem cell research of any of its member nations."

Indian Stance On Stem Cell Regulations

India, in 2007, came up with the National Guidelines on Stem Cell Research and Therapy, which was later on in 2013 and replaced by the National Guidelines on Stem Cell Research. The guidelines were the collaborative result of the Indian Council for Medical Research and the Department of Biotechnology. The 2013 guidelines outlawed stem cell therapy and permitted research in the area of stem cells. There was not much change in the 2007 and 2013 guidelines apart from the name. The 2017 guidelines brought up the mechanism of formal committee approval for stem cell activities and their periodic review and monitoring. Guidelines expressly stipulated that the clinical use of stem cells is not permitted, and stem cells must be part of clinical trials approved by the Drug Controller General of India. The guidelines provide the establishment of committees such as the Institutional Committee for Stem Cell Research and Therapy: any organization interested in carrying out stem cell activities shall be obliged to establish this committee.

National Apex Committee for Stem Cell Research and Therapy: reviews and monitors the stem cell activities at the national level and also approves, monitors and oversees the research falling under the restricted category as well as sets standards for the collection, processing and preservation of human tissues to their assure quality.
The guidelines divide stem cell research into three categories:

1. Permissive
2. Restrictive
3. Prohibitive

And bases themselves on the following principles:

1. Health and Safety of donors of the cells.
2. Manufacture and quality assurance of stem cell products.
3. Type of preclinical studies to be done.

4. Design, conduct, and monitor clinical trials are to be done.

Guidelines also attempt to resolve the patent issues regarding stem cells, but the patent clause is so vaguely drafted that it will create chaos in the near future.

The legislative force lacks stem cell guidelines. The guidelines are not binding, and no one can be punished for violating them. The guidelines are nothing but the teeth-less tiger. Another essential flaw of the guidelines is that they fail to distinguish between autologous and allogenic stem cells. Autologous stem cells are the stem cells taken from the patient's own body and administered into his own body. The process of autologous stem cells is 100% safe, and such need not be required to obtain the permission of the Institutional Committee for Stem Cell Research and Therapy.

The new Drugs and Clinical Trials Rules of 2019 attempt to regulate stem cell-related activities by including stem cells under the category of new drugs, but the rules, as per researchers' opinion, failed to attempt to regulate unregulated!

Delhi High Court, in its judgment,[19] recognized and referred to stem cells and defined treatment as "taking such steps as would not only tend to effect the cure of a disease but also steps which would prevent further deterioration of the disease." If treatment avoids further deterioration of the patient's health and maintains the health status quo, such proven or unproven treatment may be offered to the patient subject to the approval of regulating authorities. The judgment of the Delhi High Court, to some extent, supports unproven treatments such as stem cells for diseases that are declared to be incurable. The Delhi High Court's approach is a step forward in the field of stem cell research.

CONCLUSION:

The swiftly evolving field of stem cell research and therapy will continue to top the charts in medical research, placing a high demand for unambiguous rules and guidelines. The collaborative efforts taken up by the guidelines are not yielding desirable results as there is no legislative force to follow the guidelines, and both ICMR and DBT have no remittance to research activities not funded by the government.

India is a hub of In Vitro fertilization techniques. The government has liberally supported such techniques. As the whole controversy of embryonic stem cells revolves around the destruction of embryos for extracting embryonic stem cells, this can be resolved if the excess embryos created in IVF clinics are permitted to be used in embryonic stem cell research. India has no guidelines on the supernova embryos created in IVF clinics. Well-drafted guidelines for IVF with regard to embryonic stem cell research may have the potential to eliminate the ethical and legal controversy of embryonic stem cells.

India has to cover many miles as far as the regulation of stem cells is considered. In India, a lack of awareness of the stem cell policies among the stakeholders hinders the growth of stem cell research.

References :-

1. Stem Cells basics, by National Institute of Health available at https://stemcells.nih.gov/policy/2009-guidelines.htm last seen on 29/07/2020
2. 2005 ACJ 69
3. 2007 (4) ACD 835 (Andhra Pradesh High Court)
4. 2010 (3) TAC 114 (Delhi)
5. 12.1,Prohibition of Human Cloning for Reproduction Act 2002,(Australia) available at https://www.legislation.gov.au/Details/C2016C00933 last seen on 01/08/2020
6. Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006,(Australia), http://www.comlaw.gov.au/Details/C2006A00172 last seen on 01/08/2020
7. 14,Prohibition of Human Cloning for Reproduction Act 2002,(Australia)
8. 20,Research Involving Human Embryos Act 2002,(Australia)
9. European Commission Community Research and Development Information Services (CORDIS), “What is FP7?” available at http://cordis.europa.eu/fp7/faq_en.html last seen on 12/3/2017.

10. Council of the European Union, “Competitiveness (Internal Market, Industry and Research),” press release, July 24, 2006,available at http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/90654.pdf,last seen on 01/08/2020 .,
11. European Human Embryonic Stem Cell Registry, “About hESCreg,” available at http://www.hescreg.eu/index.php?id=14 last seen on 12/3/2017
12. Robert P. George and Donald W. Landry, *Ethical Considerations Regarding Stem Cell Research*,34 The new Atlanties*: A* Journal of Technology and Society, available athttp://www.thenewatlantis.com/docLib/20120125_TNA34TheStemCellDebatesLessonsforScienceandPolitics.pdf last seen on 01/08/2020
13. Robert P. George and Donald W. Landry, *Ethical Considerations Regarding Stem Cell Research*,34 The new Atlanties*: A* Journal of Technology and Society, available athttp://www.thenewatlantis.com/docLib/20120125_TNA34TheStemCellDebatesLessonsforScienceandPolitics.pdf last seen on 01/08/2020
14. Robert P. George and Donald W. Landry, *Ethical Considerations Regarding Stem Cell Research*,34 The new Atlanties*: A* Journal of Technology and Society, available athttp://www.thenewatlantis.com/docLib/20120125_TNA34TheStemCellDebatesLessonsforScienceandPolitics.pdf last seen on 01/08/2020
15. Stem Cell therapy in Neurological Disorders, 2nd Edition by Dr. Alok Sharma.
16. Human Fertilization and Embryology Act 1990, (United Kingdom), c. 37, http://www.legislation.gov.uk/ukpga/2008/22/contents.last seen on 02/08/2020
17. 4A*Human Fertilization and Embryology Act* (2008), (United Kingdom)
18. United Nations General Assembly, *Resolution 280,* Fifty-ninth session (March 23, 2005), UN Doc A/RES/59/280, *United Nations Declaration on Human Cloning*, https://digitallibrary.un.org/record/543570?ln=en. Last seen on 01/08/2020
19. Virendra Singh Malik v. Union of India , AIR Online 2019 Del 655