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[SHORT ARTICLE]

Stem Cell Regulation in India: A Toothless Tiger

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Abstract: With the introduction of the National Guidelines for Stem Cell Research, 2013, the topic of stem cell technology topped the charts of the Indian medical sector. Indian Council of Medical Research (ICMR) in collaboration with DBT outlawed the stem-cell therapy in India and dragged it under the purview of the clinical trial mechanism. The extraction of stem cells is associated with certain ethico-legal controversies and complexities, one of which is the destruction of the human embryo for the extraction of embryonic stem cells for research and therapeutic use. The debate on the said use of the human embryo is backed by religious texts of Judaism and Islam and has always been opposed by certain religious texts of Hinduism and Buddhism. In this article, the authors analyse the moral status of the embryo as well as the mechanism of regulation of the extraction of stem cells in India.

Keywords: Stem Cells; Embryonic Stem Cells; Regulations; Therapeutic Use; Self-Renewal; Specialized Cells.

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WHAT ARE STEM CELLS?

A primitive cell that can either self-renew (reproduce itself) or give rise to more specialised cell types[1] is called a stem cell.

Stem cells, having a great potential to develop into different cell types of the body, act as an internal repair system. The human body is a large group of cells capable of functioning properly. Stem cells are the initial cells that can develop into more specialised 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 due to two important characteristics. First, they are unspecialised cells capable of renewing themselves through cell division, sometimes after long periods of inactivity. Second, under certain physiological or experimental conditions, they can be induced to become tissue or organ-specific cells with special functions. In some organs, such as the gut and bone marrow, stem cells regularly divide to repair and replace the worn-out or damaged tissues. In other organs, however, such as the pancreas and the heart, stem cells only divide under special conditions. Stem cells are crucial for living organisms for many reasons. In 3 to 5-day-old embryos, called blastocysts, the inner cells give rise to the entire body of the organisms, including all of the many specialised cell types and organs such as the heart, lungs, skin, sperm, eggs, and other tissues.

Stem cells are classified as embryonic stem cells, adult stem cells, and fetal stem cells. Embryonic stem cells are derived from the inner mass of blastocyst having the potential to self-renew

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[1] Michael L. Shelanski, *An Introduction to stem cell biology*, PAPER OF COLUMBIA UNIVERSITY, (August 1,2020, 10.02 AM), www.law.berkeley.edu/files/stem_cell_day1_part2_shelanski.pdf.

and are pluripotent (cells that can give rise to all types of adult tissue cells plus extra-embryonic tissues) in nature. The controversy of stem cells revolves around the embryonic stem cells where, as soon as the stem cells are extracted from the inner mass of the blastocyst, the embryo gets destructed. This is where the ethical restraint comes into the picture. It argues that it is unethical to destroy the potential life (existing in an embryo) for alleviating the sufferer. In this debate, there are two perceptions in place. First, the use of human embryo for deriving embryonic stem cells is extremely unethical as it instrumentalises the human body. Second, the use of human embryo for deriving embryonic stem cells is not unethical provided the strict guidelines are been duly met. This debate on embryonic stem cells has brought stem cell technology into the limelight. Adult stem cells are found in organs and tissues having limited capacity to self-renew them. These cells differentiate into the cell type of which they are part of, for instance, the liver cells differentiate only into liver cells and not RBCs. Induced pluripotent stem cells are adult cells that are engineered in such a way that they start behaving like embryonic stem cells and start differentiating into any cell type. Research in the field is advancing, as these cells are a great alternative to embryonic stem cells.

RELIGIOUS VIEWS ON STEM CELLS

The debate on the extraction of stem cells mainly revolves around the grounds of morality, as the embryo is destroyed in the procedure of deriving the embryonic stem cells. Religious texts of Judaism, Hinduism, Buddhism, and Islam have expressly talked about the moral status of the use of embryo for therapeutic practices. **Judaism** emphasises upon its aim of saving life and, hence, it allows the use of human embryos for therapeutic purposes where the ultimate goal of embryonic stem cell therapy is to cure the sufferer. Judaism does not grant personhood to a fetus that is less than forty days of age.

According to **Islam**, the soul starts breathing in an embryo only after the 40th day of fertilisation and, hence, Islam does not accord the living status to an embryo until then. Islam also permits the use of embryo for stem cell research and therapy.

Hinduism and Buddhism are considered to be strict religions when it comes to the moral status of the embryo, and they do not permit the use of embryos for therapeutic purposes.

Roman Catholic, Orthodox, and conservative protestant churches accord the status of a human being to an embryo from the date of the fertilization of the egg, whereas, **less conservative protestant churches** permit the research on human embryo before the 14th day from fertilization.

This brief overview of religious views on stem cells points out the contrast among the religions on the moral status of the embryo. In a country like India, where religion plays an important role in the lifestyle of the citizens, the contrasting religious views on the status of the embryo are rather confusing.

UNBORN CHILD, POTENTIAL LIFE, AND EMBRYO- CONFLICTING STATUTORY OVERVIEW

The Indian legal system considers an unborn child and its rights in various statutes. Provisions of these statues have helped the researcher in interpreting the term "unborn child" and also "potential life in the fetus". Article 21 of the Constitution of India, which grants and upholds the right to Protection of life and personal liberty to the citizens and non-citizens, includes unborn children as well. Apart from the Constitution of India, various legislations also deal with the subject in question. For instance, Section 316 of the Indian Penal Code, 1860 punishes the person responsible for the death of a quick unborn child. Section 416 of the Code of Criminal Procedure, 1973 provides for postponement or reduction of capital punishment of pregnant women with the object of saving the potential life in

the foetus and Section 13 r/w Section 20 of Transfer of Property Act, 1882 deals with the transfer for the benefit of an unborn person.

Though the above mentioned provisions recognise the concept of unborn child, nowhere do they define the term "unborn child". Therefore, there has been some confusion regarding the legal status and personhood of the unborn child in India, but amid this uncertainty, the judicial interpretation has come to rescue. The judiciary has cautiously interpreted the concept of the unborn child in the case, Karnataka State Road Transport Corporation V. Vidya Shinde.[2]In this case, the Karnataka high court held that a fetus that has completed 37 weeks, for all the purposes, shall be considered as a child even though there is stillbirth.

In Oriental Insurance Co. Ltd v. Shantilal Patel[3] , it was held that an unborn child aged five months onwards in the mother's womb until its birth can be treated as a child in existence. Technically, the term "developing ovum" is used for referring to the organism for the first seven to ten days after conception. The same is called an embryo from one week to the end of the second month and later, it is called a fetus. It becomes an infant only when it is completely born. The court believed that the concept of the unborn child and its rights and duties will 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, shall be treated as equal to a child in existence. In Prakash and another v. Arun Kumar Saini and another, [4]it was held that an unborn child aged five months onwards in the

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[2] Karnataka State Road Transport Co. v Vidya Shinde, (2005) A.C.J. 69 (India).

[3] Oriental Insurance Co. Ltd. V Shantilal Patel, (2007) (4) A.C.D. 835 (India).

[4] Prakash and Another v Arun Kumar Saini and Another, (2010) (3) T.A.C. 114 (India).

mother's womb till its birth shall be treated as equal to a child in existence. The unborn child to whom live birth never comes can be held to be a person who can be the subject to an action for damages for his death. The fetus is another life in women and loss of fetus is actually a loss of child in the offing.

On the perusal of the abovementioned judgments, it can be concluded that a fetus aged five months and onwards can be termed as an unborn child. Hence, in conclusion, the destruction of a fetus for therapeutic use or for the extraction of stem cells before its 5th month could not be construed as the culpable homicide of potential life. The scenario (now) is clear, as the judiciary had specifically differentiated between an unborn child and an embryo. These judgments have made it clear that a woman does not carry a potential life till the completion of five weeks of her pregnancy. This, on the contrary, suggests that from the conception till the expiry of the period of five weeks of pregnancy, an embryo does not carry life within itself. Hence, this makes it permissible to support research in the field of embryonic stem cells for therapeutic practices.

These judgments by the judiciary overrule the intentions of the framers of the guidelines of 2007, 2013, and 2017. Alternatively, they permit embryonic stem cell research in a curbed manner, so that it is not considered as the homicide of potential life. The analysis of the contradiction between the judicial position and the legislative intent behind the framing of the guidelines banning stem cell therapy depicts the lack of coordination among the 3 pillars of Indian Democracy.

GLOBAL STANCE ON STEM CELL REGULATION:

A. Australia

The laws in Australia relating to human embryonic stem cell research have undergone significant changes over the past two decades. In 2002, the Australian Parliament passed the

Prohibition of Human Cloning for Reproduction Act. The Act banned all kinds of human cloning (regardless of the purpose) and also the practice of *in vitro* fertilisation for purposes other than "achieving pregnancy in a particular woman."[5]The Parliament also passed the Research Involving Human Embryos Act, 2002, which allowed the research on "excess ART embryos" if licensed by the National Health and Medical Research Council (NHMRC).

The cloning ban loosened with the introduction of the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act, 2006.[6] The Act only retained the ban on reproductive cloning to some extent, as it allowed SCNT for research purposes, as long as the cloned embryo did not grow beyond the span of 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 are exposed to similar growth restrictions, while the creation of chimeric embryos is altogether prohibited. (A "hybrid" embryo created by combining gametes or genetic material from two different species.)

B. 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,

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[5] Prohibition of Human Cloning for Reproduction Act, 2002, W.A. §12.1 (2002).

[6] Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006, S.A. (2006).

[7] Prohibition of Human Cloning for Reproduction Act 2002, W.A. §14, (2002).

[8] Research Involving Human Embryos Act 2002, W.A.§20 (2002).

[9] *What is FP7?*,EUROPEAN COMMISSION COMMUNITY RESEARCH AND DEVELOPMENT INFORMATION SERVICES (CORDIS),(March 12,2017,5.09 PM), http://cordis.europa.eu/fp7/faq_en.html.

under the Sixth Framework Program, the EU 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 EU 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 ES cell registry, which began operations in April 2007 in order to make efficient use of pre-existing ES 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 protection provided by the patent system might greatly dampen incentives for stem cell research in the EU.[12]

C. South Korea

The most recent South Korean legislation on human ES cell research is the Bioethics and Safety Act, 2008.[13]The Act prohibits human reproductive cloning and prohibits the production of embryos for non-reproductive purposes. Nonetheless, sources of human ES cells permitted under the act include SCNT ("for the purpose of conducting research aimed at curing rare or

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[10] *Competitiveness (Internal Market, Industry and Research)*, COUNCIL OF THE EUROPEAN UNION- PRESS RELEASE, (July 24, 2006,11.00AM), http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/90654.pdf.

[11] *About hESCreg*, EUROPEAN HUMAN EMBRYONIC STEM CELL REGISTRY, (March 12, 2017,8.00 AM), http://www.hescreg.eu/index.php?id=14.

[12] Robert P. George and Donald W. Landry, *Ethical Considerations Regarding Stem Cell Research,* 34 The new Atlanties*: A* Journal of Technology and Society, http://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, http://www.thenewatlantis.com/docLib/20120125_TNA34TheStemCellDebatesLessonsforScienceandPolitics.pdf last seen on 01/08/2020.

currently incurable diseases") and "spare" IVF embryos. (Only if they have exceeded a maximum storage period of five years or if researchers receive consent from their parents.) Payment for gametes is prohibited, although oocyte donors may be reimbursed for costs associated with the procedure.

The 2008 Act replaced the Bioethics and Biosafety Act, 2005,[14] which had been criticized for failing to protect not only human embryos, but embryo and egg donors as well. A large part of the 2005 Act was repealed due to the scandals surrounding the 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 in early 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]

D. United Kingdom

The U.K. has liberal regulations regarding human ES cell research. Permitted sources of ES 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),

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[14] Robert P. George & Donald W. Landry, Ethical Considerations Regarding Stem Cell Research,34 THE NEW ATLANTIES*: A* JOURNAL OF TECHNOLOGY AND SOCIETY,233-234 (2015).

[15] DR. ALOK SHARMA, STEM CELL THERAPY IN NEUROLOGICAL DISORDERS (2nd ed.).

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 carrying out research on 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 serious 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 pre-implantation 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 of the U.K. Stem Cell Bank before conducting secondary research projects on human ES cells.

E. The 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

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[16] Human Fertilization and Embryology Act 1990, (United Kingdom), c. 37, Accessed on 02.08.2020.

[17] 4A*Human Fertilization and Embryology Act* (2008), (United Kingdom).

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."

INDIA'S STANCE ON STEM CELL REGULATIONS

India in the year 2007, came up with the National Guidelines on Stem Cell Research and Therapy, which was later on (in the year 2013) 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 difference between the 2007 and the 2013 guidelines apart from the name. The 2017 guidelines brought up the mechanism of approval from the formal committee for stem cell activities and for their periodic review and monitoring. The guidelines expressly stipulated that the clinical use of stem cells is not permitted and stem cells must be a part of the clinical trials only 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. Further, the 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 categories as well as sets standards for the

[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.

collection, processing, and preservation of human tissues to assure their quality.

The guidelines divide the stem cell research into 3 categories:

1. Permissive
2. Restrictive
3. Prohibitive

Further, it stations them on the following principles:

1. Health and Safety of the 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 monitoring of clinical trials to be done.

The 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 guidelines are not binding and no one can be punished for the violation of the guidelines. The guidelines symbolize a toothless tiger. Another flaw of the guidelines is that they fail to distinguish between autologous and allogeneic 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 it need not obtain the permission of the Institutional Committee for Stem Cell Research and Therapy.

The New Drug and Clinical Trial Rules of 2019 attempt to regulate stem cell-related activities by including stem cells under the category of a new drug, but as per the researchers' opinion the setting up of the rules is a failed attempt to regulate the unregulated.

The Delhi High court in one of its judgments[19] recognised and referred to stem cells and their therapeutic use as, "taking such steps would not only tend to affect 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, such, proven or unproven, treatment may be offered to the patient subject to the approval of the regulating authorities. The judgment of the Delhi High Court, to some extent, supports the unproven treatments such as the use of stem cells for curing diseases which are considered incurable. The approach of the Delhi High Court 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 the medical industry, placing a high demand for a set of clear and unambiguous rules and guidelines. The collaborative efforts taken up by the guidelines are not yielding desirable results. Also, both ICMR and DBT have no force over the research activities not funded by the government.

India is a hub of In Vitro fertilization techniques and the government has liberally supported such techniques. The whole controversy revolves around the destruction of an embryo for extracting the embryonic stem cells, and 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 regarding the substantial embryos created in IVF clinics. Well drafted guidelines for IVF with regard to embryonic stem cell research may have the potential to eliminate the ethico-legal controversy of the embryonic stem cells.

[19] Virendra Singh Malik v Union of India, (2019) Del. 655 (India).

India has to go miles as far as the idea of perfecting the regulation of stem cells is considered. In India, lack of awareness of the stem cell policies among the stakeholders also hinders the growth of stem cell research.

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