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Commercialisation of human embryos and stem cells – A critical analysis through the rights approach

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***Abstract*---**The Multinational Corporations involved in stem cell research are lined up in the race to obtain patents for stem cells and economically exploit the patent within the time span of Twenty Years. Though stem cells have the ability to change the lives of many patients, the full potential of the stem cells is yet to be unveiled. Albeit the concerns stem cells have been used in regenerative therapies, to treat COVID-19, Parkinson diseases. Hence countries like U.S, EU, Japan, South Korea have made huge investments in Research on stem cells. However, the trepidation of morality, human right concerns on using embryos for research in stem cell industry has been criticized by human right activists, Feminists, religious leaders. This article analyses whether 'human dignity' and 'Human rights' concerns in stem cell research and commercialization can be conceded to establish 'highest standards of health' from a right based approach.

***Keywords*---**Embryonic Stem cells, Dignity, Human rights, Health, Patents.

Introduction

> *"We aren't made of drugs; we're made of cells. Stem cells, or stem cells in combination with pharmaceuticals, will be the future of medicine."* – Cade Hildreth

Stem cells are special cells that have the ability to regenerate in to human tissues and organs. Research and development in this field has increased manifolds since

its discovery in 1960. In the past fifty years stem cells have created a potential pathway to regenerative medicine.[1] The promising ability of stem cells before pandemic and its demand after the Covid Pandemic to treat Covid 19 with Mesenchymal stem cell therapy has increased the demand for stem cell research and patents all over the Globe. Many Biotechnology corporations and pharma companies are conducting clinical trials using Mesenchymal stem cells which has further piqued stem cell research. Though stem cells have proven promising abilities it has become a subject of concern because of the ethical and Human right violations that happen in harvesting stem cells, conducting clinical trials, providing therapeutic procedures and commodification through patents. This article will discuss on the ethical, moral and dignity concerns in stem cell research and its commercialization and juxtapose whether providing advanced regenerative therapies at the cost of violating human dignity must be legalized.

Stem cells and classification of Stem cells

In 1960 Stem cells were identified as special cells with the ability of self-renewal. It was first identified from "hematopoietic stem cells" (HSCs) by McCulloch and Till [2]. Later in 1976 "mesenchymal stem cells (MSCs)" were isolated from Bone Marrow by Frieden stein. In 1981, and "embryonic stem cells (ESCs)" were successfully isolated by Lotfinegad from the inner cell mass (ICM) of mouse. After which ESCs have been isolated from other mammals such as sheep, rabbits, cattle and human. In 2012 the discovery of induced "pluripotent stem cells" (iPSCs) by Shinya Yamanaka received Nobel prize , which piqued the research interest on stem cells.[3] Later, "stem cells" were isolated from blood, bone marrow, tissues , embryos. Etc. After isolation the stem cells are used in stem cell therapies which involves use of any viable human stem cell for autologous and allogenic therapies. One of the most successful stem cell treatments is bone marrow transplant of "hematopoietic stem cells" and skin grafts for severe burns.[4] Mini organoids have also been successfully produced resembling brain, kidney, lung, intestine, stomach and liver and researches are conducted in understanding the development of stem cells in to specific organs.

Even though stem cells have miraculous properties the source and the nature of evoked ethical and legal debates. "Stem cells" obtained from natural human embryos donated for research , or embryos created through invitro fertilization are known as Embryonic stem cells (ESC). *"Embryonic stem cell is a primitive type of cell that can be coaxed into developing into most of the 220 types of cells found in the human body (e.g., blood cells, heart cells, nerve cells, brain cells, etc*"[5] The embryos are formed after fertilization and in that process the cells divide every 12-18 hours. Each cleavage-stage cell is called a '*blastomere'* and the 3- to 5-day-old embryo is called a '*blastocyst'*.[6] The ESCs are obtained from Blastocyst, which if not isolated will develop in to a human life. The isolation at this stage is objected because in this process the life of the embryo is destructed which is considered unethical. However, when the ESCs are obtained from miscarried or still born fetuses, removed from live embryos without damaging is generally considered ethical whereas obtaining ESCs from aborted fetuses is considered unethical.[7] The whole conundrum surrounding ESCs are due to the prevailing variances on the Moral and ethical status of Embryo in different countries.

Countries like Turkey, Russia, Italy, Germany and Austria prohibit Embryo research, whereas countries like India, Canada, Japan, Spain, U.K permit Human embryo research with restrictions. For example, The embryos research is permitted till 14 days of its growth in U.K under the "Human fertilization and embryology Act of 1990". In Canada the "Assisted Human Reproduction Act 2004" have also incorporated the 14-day limit on embryo research. Where as in India section 30[8] of "Assisted Reproductive Technology Act 2021" prohibits sale of embryos outside India and permits research on Human Embryos within India. Section 31 of the Act, states that sale or import of Embryo is a punishable offence. The fourteen-day limitation rule was recommended because the 'Primitive streak' which marks the initial formation of human life starts to appear on the fourteenth day. Hence research before this period was technically permitted because it is a mass of cells which may or may not grow in to a life form.

However, the question is whether the 14-day limitation rule must be revisited by the international community. It is an undeniable fact that stem cell research is gaining momentum and at the same time the need to revisit the scientific policies and make adequate modifications inconsonance with the recent trends and developments is of primary importance. The moot point that the 14th day marks the origin of life was advocated since 1980 by united states, was accepted by the international community after several rounds of deliberations and it is enshrined in the legislations of the countries who were in support of it. There is no uniform legal definition for the term Embryo. For example, section 2 (f) of the "Assisted Reproductive Technology Act 2021" in India defines "embryo" "*as a developing or developed organism after fertilization till the end of fifty-six days from the day of fertilization;"* The U.K "Human Fertilization and Embryology Act" 2008 [9]does not mention about the 65-day time span for embryo. The authors argue that the 14-day time span is a compromise time span to uphold public trust and simultaneously create a balance for scientific research . The true reason behind embryo research is not clear and deliberations to incorporate them in the modern technology set up is necessary instead of blindly following the limit which was widely accepted after the Warnock committee report in 1968. "The International Society for stem cell research (ICSSR)" has been in lock step with laws, regulations and guidelines to endorse the 14-day time limit. However, the same community which was once advocating for the 14-day limit rule , In 2021 advocated for removal of the 14-day limit and have incorporated in the ICSSR stem cell Research Guidelines[10] Although it is not widely accepted , this move by ICSSR to promote research on embryo in a welcome move. Parallelly the concerns of Human dignity violations related to embryo research , non-consensual use of embryos , unethical means of procuring embryos and stem cells must be redressed.

Human dignity and stem cell Industry

'Dignity' remains as a evaluating phenomenon and a "primary justification" for the growth of science Policy. Albeit its prominent insistence and valuation, whether human dignity is infringing or degrading scientific development is rarely explained. For Example, in 2012 "President's Council Report on Bioethics titled, Human Cloning and Human Dignity: An Ethical Inquiry," has stated about dignity but did not conceptualize human dignity or address the specific ways in which

human cloning may impinge on human dignity. The UNESCR's "Universal declaration on Human Genome and Human rights" recommended a ban on all practices contrary to Human dignity including reproductive cloning.

India's "National Guidelines on stem cell research" in its general principles has stated that "*Research on human participants involving cells and tissues derived from human embryos, fetuses or any other sources must safeguard human rights, safety, dignity, and fundamental freedom"* In Canada's primary research ethics document, the "Tri-Council Policy Statement," state *that "the cardinal principle of modern research ethics, as discussed above, is respect for human dignity"*[11] However, the policies have not defined dignity. The authors have attempted to trace the developmental history of dignity, its philosophical foundations and its incorporation as a part of policy ethics.

Defining human dignity

Dignity is a concept that has many perceptions and dimensions. But unanimously Human dignity is considered as an independent moral philosophical standard based on which the structure of human rights has been built universally.[12] There are two conceptual traditions of "Human Dignity" the 'meritocratic' concept and the 'democratic' concept. The meritocratic concept can be traced back to the Roman virtue of 'dignitas', where something is offered to an individual based on the status in the society. Example Judges, Bishop, Gurus etc. or the dignity is bestowed by oneself on the basis of moral virtues. Whereas the democratic concept propounds that dignity is inherent in all human beings and not bestowed upon an individual[13]. Hence it emphasizes that Human dignity is inalienable and inviolable and all human being possess it because of the virtue of their Humanity. One of the most primary literatures referred to understand the concept of dignity is "Kantian Perceptions on Dignity".

Kantian Philosophy: Connecting Human dignity with rationality.

Immanuel Kant, distinguished between two types of things in the world: *"things with a price and things with a dignity and state that thing with dignity have moral value that cannot be measured with price* [14] Kant put forth the concept of "Categorical Imperative" (CI) based on the principle of morality as a practical rationality. "Kant characterized the CI as an objective, rationally necessary and unconditional principle that we must follow despite any natural desires we may have to the contrary"[15] Kant located human dignity as the capacity to make moral decisions.[16]

Interpreting the Kantian principles with regard to stem cells, the decision on an individual to donate an egg or sperm is a rationale decision. The consequences of the decision is not taken in to consideration but it is the moral choice of the individual where an individual decides his/ her own human dignity. Scholars such as Kant, Gewirth, and Beyleveld, have used the notion of agency to address the question of rights and emphasize that Dignity stems from the independent capacity of the individual to make moral judgements[17]. The same can be corelated to the UDHR Provision which states that *"All human beings are born free, equal in dignity and rights and recognized dignity".* The cultural values, social

norms that have been collectively accepted impose duty on the individuals to follow obligations. Human dignity is a complex phenomenon to describe in simple terms, as dignity is determined on the varied perceptions and has to be considered from the perspective of Individuals in the different status, gender, religious beliefs and moral perceptions. The authors have analyzed concept of dignity in relation to stem egg trade, embryonic stem cell isolation from the perceptions of women, religion and morality.

Egg Trade, stem cells and dignity of women

The oocyte trade was not given much consideration until the demand for female eggs increased to an extend that eggs were obtained in unethical ways to meet the growing demand. This anomaly was noticed when substantial quantities of enucleated ova were required for "Somatic cell Nuclear Transfer". Which raised the profound ethical and policy question as to how and from where the large amount of egg or ova can be collected, produced and stored to meet the demand[18]. But the debate subsided and reemerged again when large quantities of eggs were required to structure an embryo for harvesting stem cells [19]

It's an undeniable fact that in order to meet the growing demand the oocytes are harvested through various sources in unethical ways from female body, as it is considered as the easiest way to collect female eggs by paying money. Especially from women who are poor or downtrodden and those who are in need of money in the developing and under developed countries. These women have been exploited without their knowledge, as many women consider selling of female eggs as a source of income rather than a form of exploitation.

In under developed countries women are forced to sell female eggs for survival of their family, albeit unaware of the fact that it is exploitation and over extraction of oocytes will severely affect their health. For example, in Nigeria selling of female egg is voluntary and legal. Many fertility centers throughout Nigeria collect eggs from Women by paying 80, 000 Niaras to 1,00,000 Niaras for harvesting eggs in one sitting [20] More over the process involved in extracting eggs from ovary is painful, it involves three weeks of continuous drug intake which artificially stimulates the production of eggs in large quantities. More a woman donates her egg higher is the risk of cancer, ovarian failure, nervous disorders and even death because of the side effects of the fertility inducing drugs which are injected in to the female body. The eggs collected in these areas are dumped in European and American markets. In U.S donor egg banks are established to collect eggs; online application can be submitted for donating egg. Based on the nature of race, fertility and genetic make up the price of the eggs are determined. For example, An American woman gets an average of $8,000 per batch of eggs, but can ask upward of $50,000 if she's an Ivy League grad [21] where as an uneducated woman egg is prices less[22]. The price discrimination on education and talents was unheard in the medical field until the technology of disease-free egg harvest or change in mutated genetic make-up came in to existence. Now a days if there is a defect in the embryo or the parents want a specified feature or a character in a child [23] the harvested eggs are used to create or alter the embryo [24]

The willing exploitation of women for money triggers the need to understand and analyse the nature of 'human dignity'. Is human dignity Uniform, Universal and assessed with similar yardsticks globally as stated in the international conventions. Albeit its predominant emphasis, the concept of dignity has kaleidoscopic acumens. Is dignity different to different class of people? Are we moving back to the stoic principles of aristocracy supremacy? Dignity is valued based on money and with scientific technologies as tools give manipulative coercive power to human beings mostly. As rightly pointed out by C. S. Lewis as *"by some men over other men, and especially by one generation over future generation will eventually compel us to take a stand on the meaning of human dignity, understood as the essential and inviolable core of our humanity" [25]* Dignity must be viewed from the point of view of the exploited and in case of stem cell research , the value addition to eggs based on education, knowledge, skills, nationality, race amounts to discrimination and must be strictly condemned. If left unregulated the egg trade will add on to the already existing list of violation against women in its worst form.

Pricing embryos based on the race and nationality, destruction of embryos to treat infertility, Medical risk for oocyte retrieval, protection of women reproductive are issues that are mostly ignored and not regulated. very few countries like U.K, India , Germany Australia and Canada have at least put forth guidelines on collection of Embryos but not specific from the women's perspectives. The dignity concerns grow as technology grows and it is undeniable fact that all nascent technologies has to prove its necessity to overcome the ethical and moral concerns and stem cell research is not an exception to it.

Religious objections on stem cell research – The Playing God syndrome

The religious heads of Islam, Christianity, Hinduism, have strongly opposed the use of stem cells and specifically Human Embryonic stem cells. It is considered against God, Playing with God. Especially religious objections advocate the ban on Embryonic stem cell research based on the Ensoulment, almost all the religions believe that the soul is formed after 40 to 120 days and causing harm to it conscious contempt [26] Steps to destruct an embryo at this stage is soul destruction which is strictly forbidden in all religions. The late "Pope John Paul II in his 1995 encyclical, The Gospel of Life Journals" has written that *"Human embryos obtained in vitro are human beings and are subjects with rights; their dignity and right to life must be respected from the first moment of their existence."* [27].

Whereas, few liberal Christians, Jews and other religious heads support Human embryonic stem cells research as it is beneficial to Human Health. The religious objections are raised primarily for two reasons. One the destruction of Embryo is a sin and murder and second all creations must be made by God; human beings must not interfere in the creations of God. Humans are created by God and Human beings cannot play God and create or destruct or intrude in the cycle of nature. Whereas the Judeo-Christian view provide insight on Human Dignity by emphasizing human beings' connection with God: "human beings are created in the image of God". As most of the nation's create their policy's based on secular perspectives and try to exempt the religious sentiments. Fukuyama states that

Human Nature is inherent and it must not be changed. Though protecting human dignity is of prime importance, when opportunities to alleviate the human health with modern technologies is available it must not be denied outrightly without weighing its benefit to promote human health.

Human health v Human dignity – The never-ending conundrum

The preamble of the 1946 WHO constitution defines health "as a state of complete wellbeing and not just free from diseases" [28] It is further stated that "The right to the enjoyment of the highest attainable standards of physical and mental health" [29]. Further the 1948 "Universal Declaration of human rights"(Art.25) has mentioned 'right to Health' as a part of adequate standards to living. The "International Covenant on Economic, social and Cultural Rights"1966 has mentioned Right to health as a Human right. As stated in the Vienna Conference and plan of action that *"right to health is interdependent, indivisible and interrelated; violating of right to health may impair other human rights"*. Whereas this is a unique situation were 'implementation of Right to health' with special reference to 'attaining high standards of health' impairs other Human right like 'Right to protect Human Dignity', 'integrity', 'right to choose and be 'let free'. Attaining higher standards of health have been the highest priority of the human kind and it has been emphasized in various international conventions.

Martha Nussbaum states that all persons possess full and equal human dignity by virtue of their common humanity [30] Martha Nussbaum states that human life must have 10 capabilities of which life, bodily health and bodily integrity are very important. If an invention is promoting these capabilities, then it will promote the right to health there by promoting human beings to live a dignified life. So, from capabilities approach if we look at stem cell research, stem cell research promotes human health thereby promoting a way for human beings to live a dignified life. This is an approach which does not see the consequences or the cost of the stem cell research but analyses from the rights perspective which is Universal and Uniform.

Though there is no easy way out for this dilemma, the pandemic situations must also be taken in to consideration. In the current scenario, when its life-or-death situation, the scales predominantly shift only towards life. To ensure the safety of lives of crores of people all over the globe novel technologies like Mesenchymal stem cell therapies, RNA vaccines have been helpful to preserve health and life of human beings. Considering the merits and demerits of the technology and violations, prohibition of stem cell research and commercialization will not be beneficial to human kind. The International conventions and the International organizations like WHO, WTO have enshrined the principles of dignity and have made a commitment to mainstream human rights in to health care programs and have ensure National and Regional policies to consider determinants of health from Human rights approach . However, the need of the hour is to create a balance, ensuring prevention of unethical practices through proper regulatory mechanisms.

Policy ethics and stem cells

The controversies surrounding “human embryonic stem cell” is based on “the sanctity of life” and “quality of life”. The policy makers have to implement balanced regulatory mechanism to protect dignity and promote human health. Though it might difficult to suppress the debate on dignity and objections from religious and moral perspectives which affect “ordre Public” and morality, it is not impossible. Initially countries like U.S, U.K and other European countries adopted the “Sanctity of Life” and denied funding and banned research relating to stem cells. In Europe Responsible Ethical approach has been followed and every project on Embryonic stem cell must successfully pass a scientific evaluation in which the Necessity of the research and invention will be analyzed by scientific experts.

Funding and grant of patents on ESC’s are regulated by policies, guidelines, conventions and judicial decisions. Art.5 of the “European Directive on the Legal Protection of Biotechnological Inventions.” Prohibits “commercial use of the Human Body”. Avoids patentability of inventions whose industrial applications are contrary to 'ordre public or morality' (Art.6 (1) [31]. The two objections curtail the patentability of ESC in European Union but has not totally banned research on stem cell but it is cautiously permitted with restrictions in European Union. Where as in United states there were no such restrictions on patentability but the research on ESC were based on the government policies and public opinions. In 2006 and 2007 the strategy adopted by the President Bush, was to avoid encouraging unethical act of embryo destruction, albeit permit worthy cause of advanced medical research [32]. But After 2009 when Obama government lifted the ban on stem cells the “quality of life” was given predominance rather than “sanctity of life”. In few European countries [33] due to liberal regulations procurement of stem-cell research from supernumerary embryos is possible. However, in Countries like Belgium, Sweden and UK have legalized the procurement of embryonic stem-cells for creation of human embryo with strict regulatory conditions [34]

In India sec 3 of the Patent Act of 1970 enlists non patentable inventions in India. Sec 3(b) states about the ‘public ordre’ and morality objections. The destruction of Embryo Sec 3(c) restrict patentability of any living thing or nonliving thing occurring in Nature and sec 3 (j) prohibits patentability of plants and animals but permits microorganisms. Despite of the provisions more than 200 patent applications have been filed through International Patents Application system on Embryonic stem cells [35], more than 220 applications has been filed on Mesenchymal stem cells. Even though the 2005 draft Patent Manual guidelines prohibited *“the use of human or animal embryos for any purpose”* and there by preventing patentability of the same due to moral and ethical reasons, it was not reflected in the 2019 Manual.[36] The “ICMR guidelines on stem cell research 2017” in its general Principle’s state that Research on Human participants must uphold and safeguard their human rights, dignity and fundamental freedom. [37] The guidelines are discussed in detail u/ sec.4 which includes obtaining Voluntary informed consent from donors donating biological material, Following ethical and moral standards in obtaining stem cells and Maintaining quality assurance of stem cells and its derivative products.[38] Though specific legal

Jurisprudence remains gloomy the regulatory jurisprudence on stem cells tries to maintain a semblance of balance in maintain human dignity and protection India.

It is evident from the above discussions that the Ethical concerns relating to stem cells have undergone a major shift from the dignity approach to the policy approach which supports Human health. Irrespective of the limitation the common argument is that Embryos deserve respect as it has personhood and using them for experimental and scientific purposes is against humanity. At the same time the requirement to protect human dignity can imply the prohibition of commodification and commercialization of human life.

The stem cell Industry is growing exponentially because of three important reasons (i) demand for stem cell products and therapies all over the globe. (ii) Clinical trials (iii) stem cell banking. In developed countries like United states, Australia, Canada, Japan and European Union the stem cell Industry is growing because of successful therapeutic clinical trials in curing neurological disorders, orthopedic treatments, oncology disorders, cardiovascular disorders and other therapeutic applications. Whereas North America has developed as a prominent stem cell market for stem cell therapies. The developing nations in Asia pacific regions India, China, Japan, and South Korea have developed stem cell markets for collection and storage of stem cells through stem cell banking. The under developed countries in African continent have developed the stem cell markets for stem cell collection and clinical trials [39]

Legal Jurisprudence on Human dignity v stem cell

The courts tend to follow different approaches towards research and patenting of Embryonic stem cells and other stem cells. The question of dignity and the integrity of the Human Embryo , the destruction and commodification of Human embryos , patenting the process of deriving Embryonic stem cell has been viewed from varied perspectives. There were no specific conventions on stem cell Regulations but the EU Directive 98/44/EC was the first directive which laid down restrictions on Biotechnology research and inventions.

The Preamble of the EU directive emphasizes that the patent law must be applied in such a manner that the dignity and integrity of a person is safeguarded [40] Art. 6 2 (c) specifically mentioned that “uses of human embryos for industrial or commercial purposes” are unpatentable. The European court of Justice (ECJ) in the case of *Oliver Brustle V.Green Peace* [41] clarified whether the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of Directive 98/44 [42]. The ECJ emphasized the importance of accrediting human dignity and integrity to Human Embryos in any stage of development by defining an embryo and stated that any research concerning ESC cell lines are immoral as they are derived from the fertilized egg [43] but at the same time did not restrict Research on ESC. In this decision the ECJ has rightly emphasized the importance of accrediting human dignity and integrity to Human Embryos. where as in the case of *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks* the ECJ held that ESCs obtained from unfertilized Embryo can be patented. This decision received both positive and negative

comments from the scholars. The authors perceive the opinion as a welcome move which will aid in creation of regenerative medicine.

In United states as per 35 U.S.C § 101[44] patents are granted for new and useful inventions if it fulfills the trinity requirement of Patent Law. The claims relating to human beings or human subject matter though initially was denied patents, patents were given In 1996, Congress passed the "Dickey-Wicker Amendment" the Amendment prohibited NIH funding for Human Embryo research were embryos are destructed or destroyed . In 2011 the America Invents Act (AIA) restricted that patent shall not be issues to any claim which has direct or encompassing claim to Human organisms.[45] In the case of *Sherley v. Sebelius* [46] two scientists objected the NIH funding sanctioned for Embryo research and asked it to be redirected toe Adult stem cell research which was violative of the 1996 Dickey-wicker Amendment. In this case the considered whether funding of NIH and not from the perspective of whether Research on hESCs are valid [47]

Though in the Myriad Genetics case and Mayo case the patentability of biotechnology inventions improved it did not specifically discuss on stem cell Patents. In the case of *Consumer Watchdog vs. Wisconsin Alumni Research Foundation* [48] which was filed by Wisconsin to revoke the Embryonic stem cells patents issued. The court held that "the organization didn't allege any involvement in research or commercial activities involving stem cells, or that it was a competitor to the alumni organization or licensee of the patent."[49] From the above judgements it is evident that there is no Uniform global legal Jurisprudence on stem cells. The Jurisdictional Jurisprudence is guided by the National or regional Regulatory mechanism.

Stem cell Regulatory Mechanism in Canada, United states and India - A overview

The "Canadian Institute of health" developed the guidelines for the stem cell-based research in Canada. As per the guidelines a regulatory body must be appointed for overviewing the research in Canada. Stem cell Oversee Committee (SCOC) was established in Canada. SO far Canada is the only country which has a committee for overseeing the stem cell research. SCOC reviews all research involving human pluripotent stem cells. It also has a National registry of Human Embryonic stem cell research, which will help both the researchers and the people to know status of research, therapies[50]

In the United States, FDA's "Center for Biologics Evaluation and Research" regulates human cells, tissues, and cellular and tissue-based products intended for implantation and transplantation in to human recipients.[51] In India, the Stem cell Research Guidelines are silent on the establishment of a specific stem cell regulatory body [52]

In India the Efforts to regulate the stem cell Industry started in 2002 and the "Indian council for Medical Research" and "Department of biotechnology" proposed "Stem cell research in 2007" guidelines , which focused on on the monitoring stem cell related research at the National level. The 2017 revised guidelines emphasized on Mandatory registration of the Institutional Committee-

SCR (IC-SCR) and Institutional Ethics Committee (IEC) with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and Central Drugs Standard Control Organization (CDSCO), respectively. This provision has made mandatory registration of Clinical trials with the government approved organizations and committees [53] In 2019 Amendment to the Drugs and cosmetics Act 1946 stem cells are considered as "Drugs".

Hence in India, clinical trial or stem cell drug can come to the market only after the approval of the Drug regulatory authority of India In the case of ***Deepak Khosla V Union Of India*** [54] the Delhi High court passed an interim order permitting the treatment of the petitioner through "Embryonic stem cell therapy" and emphasized that the therapy must not be impeded due to changes in the regulatory guidelines. . This is a welcome move but needs more development and proper regulatory authorities who can work together. Establishment of an International registry for stem cell research will aid to ward off fake clinical trials, fake drugs, uphold human integrity and protect the vulnerable.

Conclusion

The Dissuasive claims on stem technology and its commercialization is due to the fact that the true potential of the stem cells are yet to be unveiled. Though the existing knowledge is backed by scientific evidences with an intention to revolutionize regenerative medicine and conscientious Judicious use of proven medical therapies to attain higher standards of health. The fact that in the process of creating an advanced health system ethics, morality and dignity must not be compromised as it will affect the "public ordre". The perception of evaluating health through the lens of ethics must be modified. The need of the hour is that healthcare must be viewed by the virtue of Misericordia, empathy and require simultaneous recognition of common dignity and common neediness of the existence of Human beings. Creating the common dignity perspective is only plausible through an integrated frame work that will address the inequalities of gender, equity, integrity and human rights to promote overall health and wellbeing of the human race. Creation of such a perspective and approach though may seem a distance dream, but considering the current situation where "sanctity of life" of supersedes all known concerns is not an impossible task.

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