

Stem Cell Therapies, Patient Consumers and Law – A Critical Analysis

Preetham Balakrishnan* & Dr. N.Balu**

*Research Scholar SRM School of Law, SRM Institute of Science and Technology, Assistant professor Tamil Nadu National Law university, Tiruchirappalli.

**Research Guide, SRM School of Law, SRM Institute of Science and Technology, Former Vice Chancellor NUALS Kochi.

ABSTRACT

"The regenerative medicine revolution is upon us. Like iron and steel to the industrial revolution like the microchip to the tech revolution, stem cells will be the driving force for this next revolution"- Cade Hildreth

The 'advent of novel technologies' in medical field are scrutinized through the lens of morality, ethics, necessity, efficiency, cost and cure ratio etc., stem cell industry does not fall an exception to it. Though Right to Health care is a Human Right, it is point of concern that in the process of availing that Right Ethical, Legal and Human right violations have to be borne by the "patient Consumers" to seek cure. The eye-catching advertisements, Taglines, success stories in televisions, social media platforms lure the public to undergo stem cell therapies and treatments. But the other side of the story is that 90% of the treatments and therapies are not proved and there are known and unknown risks to the people who undergo these services. Especially in case of the Stem cell therapy centers the patients have filed suits for deficiency in services, failure for non-disclosure of side effects, physical loss of body parts or even life. This raises a question of concern whether the treatment of patients have become more consumer centric rather than patient centric in the current scenario.

This article discusses the concern of mistreatment of the "Patient Consumers" and the need to address the concerns of Exploitation, fake clinics, unapproved/ unregulated stem cell therapies at the earliest. The article also discusses on the existing U.S Regulation and Indian Regulations and emphasizes the need to fill the Regulatory vacuum to address the concerns of the "Patient Consumers" and the immediate need to peg the holes in the course of availing stem cell treatments.

Key words – stem cell therapies, consumer protection, unproven technologies, unfair trade practices.

Introduction

Stem cells were discovered by Ernest McCulloch and James Till in 1960 and they identified special cells in their early stage of development that had the ability to develop into any cell based on the requirement of the body. Based on the ability of the cells to nurture, regrow, divide and develop stem cells are classified as Pluripotent stem cells and multipotent stem cells. From 1960 to 2005 Research and development in the stem cell sector increased manifold and paved way for establishment of a vivid stem cell research Industry all over the world.(1)

In 2006 with the help of advanced scientific technologies, induced pluripotent stem cells (iPsc) were created by genetical reprogramming(2). After 2006 'oligopotent', 'unipotent' and 'totipotent' stem cells were discovered which had even more promising abilities to cure diseases. When Nobel Prize was awarded in recognition of work on reprogramming adult stem cells to Sir John Gurdon and Dr. Shinya Yamanaka, the whole world conceded the power of stem cells and its successful future avenues, despite of the ethical and legal issues surrounding the invention.

The promising ability of stem cells to cure Parkinson's disease, and the need for novel treatment to cure new diseases led to the development of stem cell Industry and today the stem Industry has been estimated to reach a market value of U.S 270.5 Billion by 2025, which is predicted to annually increase at a growth rate of 13.8% from 2017 to 2025 as per the Global stem cell banking market report -2017(3). The value of the stem cell markets have increased manifold due to its high demand despite of the ambiguity revolving around the success and efficiency of the treatment as the use of stem cells in health care industry has become inevitable.

Use of Stem cells in health care industry:

The characteristics of stem cells make them more valuable in modern medical history and provide opportunities to develop new therapeutic strategies in clinical practice(4). Researchers involved in stem cell state that stem cells are the future medicines and it will revolutionize the health care industry. Researcher Azararof has stated that stem cells have enormous potentials and it will help in understanding the biological features of complex diseases.(5). Stem cells are utilized in the predominantly in the following ways;

1. **Stem cell as a tool to identify the source of diseases:** when any disease or ailment requires a treatment for which drugs or not invented or for such diseases which requires further Research and development

, stem cells act as source of research. The stem cells are isolated from the affected individuals and the possibilities of cure or its improvised phenomenon and cures are identified.

2. **Regenerative medicine:** Stem cells with the combination of other scientific technologies like synthetic biology, nanotechnology, biotechnology(6), Artificial intelligence are used in the process of regeneration, regeneration and replacement of human organs. Stem cells are used to treat lung diseases and can be used as vectors in therapeutic procedures(7), 'USC's Chang Stem Cell Engineering Facility, McMahon's lab claim that they have successfully created organoids which resembles human kidney'(8). 'The research has also been extended in creating other human organs like heart, human muscles, skull sutures etc.'(9). Though it is in its primary stage in the laboratory phase only it has created expectations in the Health care industries and consumers as miracle procedure.
3. **Stem cell therapies:** "The American society of Gene and Cell Therapy" defines "Cell therapy as the administration of live whole cells or matured cells of a specific cell population in a patient for the purpose of medical treatment"(10). Different kinds of stem cells such as "Induced pluripotent stem cells" (IPsec), "Embryonic stem cells", "Hematopoietic stem cells" (HSTC's), 'Mesenchymal stem cells' etc. are used for treatment. "(11). Every year around 25,000 hematopoietic stem cell transplantations (HSCTs) are performed every year for the treatment of lymphoma, leukemia, immunodeficiency illnesses etc.,(12)

"For practical purposes, human embryonic stem cells are used in 13% of cell therapy procedures, while fetal stem cells are used in 2%, umbilical cord stem cells in 10%, and adult stem cells in 75% of treatments". To date, the most relevant therapeutic indications of cell therapy have been cardiovascular and ischemic diseases, diabetes, hematopoietic diseases, liver diseases and, more recently, orthopedics. "In case of therapeutic procedures there are three types of therapies that can be performed using stem cells.

- a) Stimulation of endogenous stem cells using growth factors, cytokines, and second messengers, which are able to induce self-repair of damaged tissues or organs.
- b) Direct administration of stem cells so that they differentiate at the damaged or non-functional tissue sites.
- c) Transplantation of cells, tissues, or organs taken from cultures of stem cell-derived differentiated cells"(13)

Though stem cells therapies have come in to the market, it requires experienced technical staffs and doctors to provide the therapy. More over now a days because of direct- consumer marketing strategies consumers are well aware of the new technologies and diagnostic tools which are launched in the health care industry. Hence Consumers demand the therapies to be performed without thinking about the genuineness and the authenticity of the therapies.

Stem cell patents, stem cell therapies and Consumer Risks

The U.S Food and Drug Administration, FDA(14) has warned the public to verify whether the stem cell Therapies have been approved by the FDA(15). The private health care sector is marketing the 'stem cell therapies' without proper evidentiary proof and have not only created demand in the domestic markets but also in many developed and high-income countries. when there is greater demand in the market for the products that are still in clinical trial stage, they reach the market by hook or crook. More over when a particular technology is patented the patent is valid for 20 years from the date of filing. Hence, the patent holder can only exploit the invention within the limited time span. In order to receive the maximum benefits within the granted time limit, the patent holder or the licensee of the particular patent would be highly interested to economically exploit this opportunity. Though most of the stem cell therapies or drugs are still in the Clinical trial stage there is great demand in the market. So, without informing the public about whether the stem cell therapies have been properly approved after completion of appropriate and necessary clinical trials they are advertised to make the consumers inquisitive about the product there by increasing the demand for the new product. The inquisitive consumers undertake the unproven stem cell therapies due to lack of knowledge. Most of the stem cell therapies are administered in the unregulated private clinics subjecting the consumers to the following risks.

1. **It takes away the Choice of the patients** and make them desperate for cure without explaining the risks of side effects.(16)
2. **Violation of rights in the name of Contribution to research:** Jeremy sterner and Leigh Turner in their research study report(17) state that the 'Stem cell advertisers' made the contributors to believe that they are campaigning for a positive cause and there by contributing to science and medical field. Campaigns were made in the following ways:
 - i) The clinical trial will contribute to the FDA approval. So be part of the clinical trial and help in getting approval for the treatment
 - ii) The person undergoing treatment in a private clinic shall appeal to other with the same ailments / disease to participate stating that they Can sacrifice for the sake of helping thousands of patients.
 - iii) Participate and help us study on the stem cells.

The research report has highlighted the market reality. It is very evident that in the name of contribution to research , the participants are coerced and subjected to be a part of the research , which is a clear violation of the individual rights. The right to choose and try medical treatments are taken away and they are coerced to become scape goats in the research.

3. **High Price tags** – As there is huge demand, despite the chance of failure of treatment or side effects the patients are heavily charged. For Example, in United States, Advertisements for treatment of Osteoarthritis (OA) is offered at a cost ranging from \$1500 to \$12,000 with an average of \$5000(American academy for orthopedic surgeons). Though the clinics claim 80% success, it's not supported by substantial evidence. It also forces the patients who are in financial crisis to force spend on these therapies , which psychologically affects the patients and families and make them debtors.
4. **Adverse side effects:** The treatment providers unscrupulously operate with **over sightedness** and even when the consumers are genuinely affected blame it on the risk factor or as an unknown side effect which has occurred in a special case. "In Bone marrow stem cell transplant adverse effects like infections, short term side effects like soreness, diarrhea, nausea and long-term side effects like thyroid, cataract, infertility, lung and bone damage, can occur"(18). In Mesenchymal Stem cell therapies side effects and complications are at higher level. one patient who underwent a 'Mesenchymal Stem cell therapy' developed a large tumor-like mass inside the spinal cord after 8 years of olfactory mucosa cell transplantation(19). The effects can be determined with time constrains or it may develop at any time, though other factors like the immunity, body conditions, other conditions also play a vital role, the side effects of stem cells are abstruse and may develop at any point of time sooner or later. It is the duty of the service provider to describe the risks to the patients, but whether it is strictly followed is still a question .
5. **Victims of unproven clinical trials:** Stem cell therapies before coming in to the market must be clinically tested and the testing centers recruit the patients to undergo treatment as a part of clinical trials if they are unable to pay money, or in desperate need of treatment. It is mandatory to obtain consent after providing the overall pros and cons but the centers in most of the cases provide false information to the recruits and obtain consent for clinical trial. In United states noble a retired university professor went to stem cell clinic in sunrise, Florida where she paid 5000\$ to remove fat from the abdomen and to insert the mixture of plasma in both the eyes. After three days her retina bled and the doctors said that she was legally and functionally blind. The therapies offered were unproven and un approved by FDA(20). The author has mentioned about incident, which was reported, but there are many who fail to report or enter in to compromise settlements rather than reporting the incidents to the authorities.
6. **Lack of awareness to report legal cases:** Even when the consumers are affected after receiving treatment, consumers are hesitant or not aware of the legal provisions, approachable authorities and legal regulations. As a result of which more cases are unreported.

7. **Consumer Exploitation through Stem cell tourism:** When patients who are unresponsive to conventional therapies and treatment travel to other countries in search of stem cell therapies it is called as stem cell tourism. In order to expand the business in this industry, the service providers exploit the weaknesses and differences in National regulatory infrastructures(21).In stem cell tourism unethical practices and unproven technologies are provided as the service providers are mostly profit minded. The clinics and the service providers market the procedure at the cost of up to 80,000\$ not including travel expenses(22).

The service providers recruit portals to feature drop down menus of many incurable diseases and disorders including autism, cancer, diabetes, dementias, Lyme disease and spinal injury. The advertisers lure the consumers by portraying their 'clinical rigor' by falsely advertising and falsely claiming the merits of the other researchers and free ride on their goodwill. Further the patients have underlying financial risk, adverse side effects risk, travel risks, clinical risks etc. Though consumers are widely affected in most of the stem cell tourism destinations the stem cell industry is mostly unregulated and it is very difficult to protect the consumers and punish the unauthorized clinics. When the developed countries started implementing strict guidelines , consumers fled to developed and underdeveloped countries in search of stem cell therapies which had weak or no regulatory mechanisms in search of cure (22)which was termed by Cohen as "Circumvention tourism".(23)

Though there are consumer risks, when a patient voluntarily agrees to endure the unendurable for cure, can the law restrict the treatment by banning unproven stem cell therapies or Rogue clinics. This is difficult question to answer , though the patient has every right to try for a cure, but at the same time it's the duty of the government to regulate and approve the available therapies and cures in a country in order to protect the patients from deception .It's obvious that patients practice Circumvention tourism and try to evade the rules and Regulations in search of Cure. The Surveillance and monitoring of the authorities and strict Regulatory mechanism will deter the unauthorized service providers, especially in case of new therapies . The Researcher has analyzed the Existing regulatory mechanism on stem cell research and therapies in United states and India to understand the Existing system in both the countries to protect the patient consumers

Existing regulatory mechanisms to curb and protect stem cell therapy anomalies:

Position in United States

In United states thousands of Rogue clinics have mushroomed all over the country and the unscrupulous actors have seized on the clinical promises of regenerative medicine and are exploiting the uncertainty by making false, deceptive, corrupt assurances. They promote unproven procedures and offer expensive procedures to patients which are dubious or unproven with little hope. These activities make the consumers question the genuineness of the reliable products created with sweat, hard work, sincerity.

Regulatory mechanism for stem cell marketing in United States

In United States if any stem cell advertisement without scientific evidence is advertised the companies will be sued by FDA on the grounds of false advertising and defective practices affecting commerce's under the "Federal Trade Commission Act". Sec.5 of the Act, prohibits unfair trade and deceptive practices that "unfair or deceptive acts or practices in or affecting commerce" and Sec.12 prohibits "dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services or cosmetics."(24)

Medical treatment claims for the stem cells, also have regulatory implications under the 'Federal Food, Drug, and Cosmetic Act (FDC Act)', 'The Public Health Service Act (PHS Act)'. As an initial matter, amniotic stem cells would constitute Food and Drug Administration (FDA) regulated "human cells, tissues, or cellular or tissue-based products" (HTC/PS). **The** FDA has also issued guidance documents about how the drug, biologic, and device regulations apply to cellular and genetic therapies.

Role of FDA in regulating Stem cell clinics and consumer protection in United States

In United states FDA (25)approves all the stem cell therapies that have successfully completed the clinical trial proceedings and are ready to be launched in the health market or a clinical trial must be studied under an Investigational New Drug Application (IND) submitted to FDA (26).The FDA evaluates the process, product safety, purity, potency and safety aspects and other preliminary research reports on animal studies.

In 2016 December 21st **Century cures Act** was passed by the congress to regulate the innovations relating to Regenerative Medicine and therapies. Under the Act sec.3031 to sec.3036 mentions with regard to the patient Access to therapies and information. As per the provisions FDA is authorized to regulate the inventions, therapies and Medicines relating to Regenerative Medicine and has issued powers to the FDA to draft policies, rules and regulations with regard to the Standards for Regenerative medicine and advanced therapies. FDA published ["Expedited Programs for Regenerative Medicine Therapies for Serious Conditions, Evaluation of Devices Used with Regenerative Medicine Advanced Therapies"](#)(27) The Final Guidance as mentioned in section 3034 with regard to the 'Regenerative Medicine Advanced Therapy and Designation (RMAT)' with regard to isolation, delivery and recognition of RMAT has been issued by FDA.

FDA also publishes the list of stem cell therapies/ drugs that have been approved by FDA in the FDA website. If clinical trials are not conducted through IND, FDA has not reviewed the therapy and the service provider cannot falsely advertise regarding the FDA approval. When stem cells were launched initially there were not many regulations regarding its advertisements as marketing the new invention was the primary agenda. But recent empirical research conducted in developed countries shows that despite of strict regulations in U.S, Japan and Australia the powerful advertising claims and campaigns through direct-to-consumer methods lack efficacy and conclusive proof (28) FDA Acting Commissioner Ned Sharpless, M.D. stated that *"We've made it clear to the industry and the public that while we are taking a risk-based approach to regulatory actions, the FDA will continue to protect patients from the most egregious actors in this field. We will prioritize appropriate regulatory actions against those who place people's health at risk by promoting unapproved products"*(29). The Judicial Decisions in case of irregularities in stem cell therapies and false advertisements have Judiciously looked upon the reasons, nature of irregularity, the Loss suffered by the patients, the Fulfillment of the mandatory Regulations put forth by the law . In In the case of **Lee v Human Biostar** (30) the patient was treated for arthritis, diabetes and High Blood pressure using stem cell infusion and injection in to the knee. The Patient was not properly informed regarding the procedures and its outcome. Human Biostar was sued for Misrepresentation, false advertising, negligence and financial elder abuse.

United States v. Regenerative Sciences the defendant company created the Mesenchymal stem cells , further for the treatment they extracted and isolated bone marrow from the patient and used it to create Mesenchymal stem cells for treatment at a cost of \$7000 to \$9000 (31) Despite of providing unproven stem cell therapy without the FDA approval they have provided the service at a very high price. The FDA sent a warning letter to the company Celltex to stop the procedures.(32)

In the case of Hones v Young, Ms. Hones agreed to undergo unapproved stem cell treatment under Dr. Young, a Ph.D. Scholar at Biogenies Institute. After the treatment Ms. Hones health deteriorated and she died. The doctor and the institute were sued for breach of fiduciary duty, lack of informed consent, loss of consortium, fraud intentional misrepresentation and negligent misrepresentation of facts. In all the above cases the U.S courts have always tried to grant remedy to the Victims. The desperate patients try to find cure one way or the other and are not concerned about the approval of the therapy or treatments. on one hand the FDA is issuing stricter guidelines to curb the usage of unapproved stem cell therapies at the other end the infringers use the online service providers to propagate and solicit customers through misleading advertisements.

Mis leading Advertisements, online service providers Liability:

It is the right of any service provider to advertise about the product or therapies that are made available and stem cell do not fall exception to it if it is approved by the appropriate authorities. But for the sake of soliciting consumers false or misleading advertisements cannot be used as a tool to deceive consumers and free ride on the good will of the Internet service Providers especially the search Engines. The FDA has issued strict guidelines to the online service providers to ban unproven medical treatments. In 2019 Google developed a

policy to ban advertisements on unproven medical treatments including stem cell therapies(33). This policy of Google was appreciated by Deepak Srivastava president of International Society for Stem cell Research (ISSCR). He further stated that this advertisement ban by Google will help curb unproven medical products and unproven stem cell therapies(34). In United states the Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ)(35) have tightened the reigns of the Rogue Clinics and have created strict Regulatory mechanism for screening, approval, advertising of stem cell therapies and treatments.

Position 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 a guideline on Stem cell research in 2007. The 2007 guidelines primarily focused on the monitoring of research and therapy for stem cell related products in India in Institutional and National levels. But stem cell Industry needed a much stronger legal frame work with penal provisions and regulatory authorities. The Stem cell guidelines have been modified and the recent version of the research guidelines were published in 2017.

The “National Guidelines for Stem cell research 2017” has the following important provisions in order to protect the interest of the consumers.

1. All clinics involved in stem cells must be registered with the ‘clinical trial registry’.
2. Stem cells cannot be marketed without appropriate license and successful completion of clinical trials.
3. The guidelines prohibit the commercial use of stem cells.
4. False or misleading advertisements regarding stem cells are prohibited.
 - i) “Chapter 6 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002” – mentions about the Unethical acts that a physician is prohibited from performing which includes advertising of medical services and medical products. In case of Violation the IMC can take appropriate action.
 - ii) Under the ‘Drugs and Magical Remedies (The Objectionable Advertisements) Act- 1954’ all misleading advertisements that proclaim magical cures and remedies through drugs are prohibited. In case of Violation the ‘Director General of Health Services’ and relevant state authorities are mandated to take necessary action for this violation which will amount to imprisonment up to 12 Months, fine or both.
 - iii) The advertisement claiming available cure for several diseases as listed in Schedule J of ‘Drugs and Cosmetics Act, is not permissible.
 - iv) Any Advertisement that violates the code for self-Regulation in advertising as adopted by ‘Advertising Standard Council of India (ASCI)’ shall not be permitted.
 - v) The regulations also have recommended to establish a separate regulatory authority under the National Guidelines(36)

Under ASCI Consumer complaints Council(CCC) grants redressal to the Complaints filed against ‘false and misleading’ advertisements. In 2013 the CCC banned the advertisement by a popular clinic which claimed use of stem cell therapy for Acne”(37) without any evidentiary support. Another Advertisement claim by a famous company on use of baby’s Umbilical cord which cures 80 life threatening disease and implied on the stem cell therapy was considered violation of the National Guidelines for Stem Cell Research 2013(38) In 2015 the Ministry of Health and Family welfare has processed 23 complaints on website advertisement claiming to cure incurable disease with the use of stem cells. The ICMR has looped in ASCI to monitor the claims on cure using ‘stem cell therapies. Dr. Alok Srivastava, Chairman, NAC-SCRT said, “Advertisements claiming to offer stem cell-based therapies other than Haematopoietic Stem Cell Transplantations for blood diseases are in violation of the clause 10.3.1 of the National Guidelines for Stem Cell Research-2013.”(39) In 2019 out of the 377 complaints dealt by the CCC, 29 were related to health care. A hospital advertised the use of stem cell therapy to cure infertility which was for unapproved indications was also banned and considered in Violation of National Guidelines for Stem Cell Research 2013.(40)

Recent Regulatory Reforms with regard to stem cell Industry in India :

Sugam Portal

One of the effectively implemented proposal by the NITI AYOOG is the SUGAM PORTAL which facilitates the online Application and Grant of Licenses for Drugs by the CDSCO and further it also facilitates voluntary data submission with respect to licensed manufacturing units and drugs by self-declaration by the manufacturers on the SUGAM portal. This portal has facilitated the manufacturers to apply and obtain Licenses without much hassle. The data base facilitates data approval and data viewing about the multiple licenses granted to a single manufacturer which is helpful both for the state authorities and also to the manufacturers(41).

Amendment of the Drugs and Cosmetics Act 1945 :

In 2018 The Drugs and Cosmetics Act 1945 was amended and stem cells are added as Stem cell Drugs in India. 'Drugs and Cosmetics Rule, 1945' State that **"when a stem cell is more than minimally manipulated and substantially manipulated shall be considered as stem cell drugs whereas minimally manipulated stem cells will not be considered as 'a Drug' will be excluded from the Drugs and Cosmetics Rule"**. So, it is necessary for any stem cell related product to be backed by successful clinical trials in order to prove the safety and efficacy of the products, only then the producers of the drugs can issue licenses. Only clinics that have successfully completed and followed the rigorous standards prescribed for clinical trials and have sufficient proof to prove that their 'stem cell therapies' work can administer the treatments. In India at present only 'hematopoietic stem cell' transplants for blood diseases and 'limbal stem cell transplants' for corneal diseases are permitted. All other forms of stem cell tissues can only be used only after obtaining prior approval and registration with ICMR registry.

An Apex Authority "National Apex Committee for stem cell research" has been established at the National Level to monitor the stem cell Research Activities and at the Institutional Level "Institutional committee for stem cell research" to monitor the stem cell Research at the Institutional Level . Both the committees are watch dogs one at the National Level and the other at the institutional level to monitor the Stem cell Research in India. After research the stem cell products must undergo a clinical Trial in compliance with the new "Drugs & Clinical Trial Rules 2019". The " Central Licensing Approving Authority" under the Central Drugs Standard Control Organization(CDSCO) grants licenses for manufacturing, under taking Clinal Trials, Importation and Distribution of stem cell Related products in India . CDSCO the Indian Regulatory body for can be considered as an organization similar to that of FDA in India. It further Streamlined Stem cell and cell-based research approval by authorizing the National level Cell Biology Based Therapeutic Drugs Evaluation Committee (CBBTDEC) as the single committee to grant approval instead of the earlier three-step approval process.

Stem cell therapies and Consumer protection in India

'The Consumer Protection Act' was drafted in 1986 and it was amended and the new Act came in to effect in 2019. The New Act was equipped to address the technical concerns of consumers while availing e commerce, online services and direct to consumer services. The Consumer protection Act was drafted with the primary aim to protect the consumers and grant simpler and quicker redressal. When any stem cell related products or therapies are offered without prior approval or with authorization in accordance with rules prescribed can be considered as Unfair trade Practice under the 'Consumer protection Act' under section 2(6). It is the 'right of the Consumer' to be protected against 'marketing of goods which is hazardous to health and safety of life', 'protected against unfair trade practices', 'right to be assured, heard, seek redressal and consumer awareness'.

The Act also guarantees protection for 'misleading advertisements' which propagates false information, claims, promises with regard to the quality, safety, efficacy of the treatments. So **"When any stem cell clinic falsely propagates about the stem cell drugs and offers stem cell therapies which are defective, clinically not approved, deficiency in service can be considered as Unfair trade practice and false representation of goods"**. If any consumer who has undergone treatment after falling prey to the advertisement then they can approach the consumer redressal forum.

In the case of **Yogesh Nirmala v Union of India** and **Kala Chand v concerned authority under infancy health care**(42) the issue was whether there were any unfair trade practices or deficiency in services on the part

of the clinics towards the consumers. The Consumer forum held if an individual has signed the consent form which stated that the results may vary from patient to patient. The complainants cannot question the efficiency of the therapies and hold them liable for providing deficiency in services. If unproven stem cell therapies are used without informing the consumer then the consumer can claim damages for falsification of information in the advertisement and claim it as unfair trade practice.

In the case of **HM shivmurthy V-V-3 Slim Care**(43) based on a newspaper advertisement which stated that the clinic will provide treatment for baldness using stem cell therapy. The promise of long hair within a few weeks of treatment was mentioned. The Plaintiff sued the defendant under section 12 of the Consumer protection Act for Deficiency in service provided. But the court held that stem cell therapy depends on various individual medical conditions and hence it alone cannot be treated as deficiency in service and the case was dismissed.

Analysis of the Indian Scenario:

In United states , the Regulations on the Regenerative medicine are monitored by FDA. In India the CDSCO is a regulatory authority similar to the FDA. FDA acts as a single Regulatory authority and all the regulations and approvals relating to food and drugs are monitored and further, they are equipped with regulatory and enforcement powers. The warning letters are issued to the wrong does to correct and incase of repeated errors appropriate regulatory actions are initiated. Though the CDSCO is equipped with the regulatory powers and the ICMR is drafting and amending new rules and regulations to cope up with the technological needs and changes , many 'Rogue clinics' are slowly growing up in India and have acquired consumers through various modes of solicitation. The Union Minister Union Minister of State for Health and Family Welfare Ashwini Kumar Choubey informed the Lok Sabha that the Indian Council of Medical Research (ICMR) has received several complaints against the misuse of stem cell therapy and the Apex Committee for stem cell Research and therapy is looking at it and forwarding its recommendation to the appropriate authorities. In order to overcome the issues, the Minister further stated that the ICMR guidelines shall be amended to address the short comings on the stem cell misuse and stem cell banking and storage(44). This statement emphasizes the significance of the need for amendments to the guidelines and supports the authors claim for amendments to the ICMR guidelines.

Further in India , there is no clear distinction between the approved and unapproved stem cell therapies. The Remedy provided to consumer in case of approved therapy must be distinguished from use of unapproved therapy. The use of unauthorized therapies must be considered as a serious crime , as it happens with an intent of deceit . Were as in case of authorized therapies, there is no intent of deception , but the adverse effects may vary from patient to patient. It is pertinent to note that this distinction will clearly be helpful to the consumers and also to the service provers. The Government must Amend the existing regulations to make it mandatory to notify the list of approved stem cell therapies in the CDSCO website , so that it will be easy for the consumers to verify the genuineness of the therapy. The existing method of guideline-based approach, without classification is insufficient to curb the menace with the mushrooming unauthorized 'stem cell clinics' and 'stem cell therapies' every year. Dr Geeta Jotwani, Deputy Director-General, ICMR, who drafted the National Guidelines for Stem Cell Research, said: *"We have been continuously receiving complaints against stem cell banks that unscrupulous entities are luring people in to stem cell therapies"* The News Report further stated that the Number of stem cell therapy clinics have increased in Bengaluru and the stem cells were initially stored for individual purposes and now it is stored for community purpose. Dr.Geeta Jotwani also mentioned that the ICMR is coming up with the guidelines for approved and unapproved stem cell therapies (45)If the regulations are amended, it might be helpful but still not be efficient to curtail the menaces without a strong enforcement authority.

With regard to the false advertising, voluntary steps by the online service providers like GOOGLE to prevent false advertising can be helpful but cannot be stopped without strict legal back up. In India there is a need for a separate legislation equipped with enforcement authorities to resolve the issues in stem cell Industry more efficiently .Though there are regulations there is no strict Regulatory Frame work specifically to address the issues relating to stem cells. Though ICMR frames the guideline the appropriate actions cannot be

initiated against the wrong doers and grant Justice to the infringed and so the regulations and the monitoring authority can be considered as fierce but toothless to leave a bite. Hence it is of vital importance to address the issues relating to stem cell Industry and created a separate legislation to address the concerns of the Patient consumers in India.

Conclusion: Despite media hype, scientific over claim and unrealistic expectations, which have been previously witnessed for a number of healthcare technologies, regenerative medicine continues to make steady progress and the same can be witnessed by the successful stem cell therapy treatment used by UAE to treat COVID positive patients. There is a need to balance the acceptance of new technologies like stem cell therapies in the health care treatment and to protect the consumer from exploitation. In order to achieve the balance public awareness, public acceptance and self-regulation of the stem cell industry guided by appropriate regulatory authorities will pave way to bridge the gap.

Despite of the uncertainties in the usage of approved and unapproved stem cell products the novel drug 'stempeucel', which received a stem cell process patent in 2015 in China(46)and the U.S patent for the method of the treating Critical Limb Ischemia (CIL) by administering pooled allogenic mesenchymal stromal cells in 2019 has received its approval in India . The Drug Controller general of India has issued regulatory approval for CIPLA by granting Exclusive marketing rights for Distribution of the Drug in India to treat CIL disease. 'Stempeucel' is the First stem cell-based drug that has been permitted to be distributed in a commercial scale. The price of the drug, affordability and issues relating to its usage and efficacy in India is still unclear. But it is evident that the demand for cure through stem cell therapies / products has overshadowed the other concerns and has emphasized the need for a strong central regulatory authority to monitor the Research and use of stem cell related products in any country. The existing regulatory authorities are taking essential steps to cope up with the irregularities in the stem cell industry and are trying to fit the round peg in a square hole.

References:

- 1) Biehl, Jesse K, and Brenda Russell. "Introduction to stem cell therapy." *The Journal of cardiovascular nursing* vol. 24, 2 (2009): 98-103;
- 2) <https://stemcells.nih.gov/info/basics/6.htm> visited on 21-04-2020.
- 3) Stem cell market trends and growth report, www.modorintelligence.com, 09-04-2020
- 4) Kolios George, Moodley Yuben, Introduction to stem cells and Regenerative Medicine, Thematic review series, *Respiration* 2013;85:3-10.
- 5) See, "We believe stem cells have enormous potential in health and medical research and recognize the potential of stem cells both as therapeutic and technology platforms. Application of stem cells directly derived from patients in Research and development efforts, especially combined with other emerging innovative technologies will help us to understand the biological process that underlie, any complex diseases as Alzheimer's".
- 6) Jessop, Zita M et al Transforming health care through regenerative medicine, *BMC medicine* Vol.14, 1 115 10 Aug 2016
- 7) Sage E.K., Loebinger M.R., Polak.J and Janes, S.M, The role of bone marrow- derived stem cells in lung regeneration and repair (September 30, 2008), *Stem*, ed. The stem cell research doi /10.3824/stembook.1.20.1, <http://www.stembook.org>.
- 8) Cristy lytal, growing hope: New Organs? Not yet but getting closer. <https://stemcell.keck.usc.edu/new-organs-not-yet-but-stem-cell-research-is-getting-closer>. 27-10-2018 visited on 21-04-2020
- 9) Id.
- 10) Sharma Alok , Ziad M AL Zaoubi " Rethinking on ethics and regulation in cell therapy as part of Neurorestoratolog", *Journal of Neurorestoratology* 2016:4 .<https://www.neurogen.in/assets/frontend/pdf/scientific-publications/Ethics/01-Ethics.pdf>
- 11) Liras, Antonio. "Future research and therapeutic applications of human stem cells: general, regulatory, and bioethical aspects." *Journal of translational medicine* vol. 8 131. 10 Dec. 2010
- 12) Id.
- 13) Id.

- 14) FDA – Federal drug Authority, U. S Department of Health and Human services.<https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies> visited on 21-04-2020
- 15) Tsung-Ling Lee,el “ World Health organization Bulletin”vol.95 September 2017. <https://www.who.int/bulletin/volumes/95/9/16-189977/en/> visited on 24-04-2020
- 16) Snyder Jeremy, Turner Leigh, Regenerative Medicine Regen. Med. (2018) 13(4), 375–384, <https://www.futuremedicine.com/doi/pdf/10.2217/rme-2018-0007> visited on 21-05-2020
- 17) Side effects of a bone marrow transplant, ASCO Journals, approved by cancer.net editorial board 2019, <https://www.cancer.net/about-us/cancernet-editorial-board>
- 18) Barbara Lukomska, Luiza Stanaszek, Ewa Zuba-Surma, Pawel Legosz, Sylwia Sarzynska, and Katarzyna Drela, “Challenges and Controversies in Human Mesenchymal Stem Cell Therapy,” Stem Cells International, vol. 2019, Article ID 9628536, 10 pages, 2019. <https://doi.org/10.1155/2019/9628536>.
- 19) United states of America v U.S stem cell clinic ,LLC & others Case 0:18-cv-61047-UU 2018
- 20) Master, Zubin, and David B Resnik. “Stem-cell tourism and scientific responsibility. Stem-cell researchers are in a unique position to curb the problem of stem-cell tourism.” *EMBO reports* vol. 12,10 992-5. 30 Sep. 2011, doi:10.1038/embor.2011.156.
- 21) Charles E. Murdoch & Christopher Thomas Scott (2010) Stem Cell Tourism and the Power of Hope, The American Journal of Bioethics, 10:5, 16-23, DOI: 10.1080/15265161003728860,www.tandfonline.com<https://doi.org/10.1080/15265161003728860>
- 22) Id.
- 23) Elanie Mc Ardle , Ethics health law and policy international, Harvard Law Bulletin summer 2013. <https://today.law.harvard.edu/feature/patients-without-borders-i-glenn-cohen-on-the-rise-of-medical-tourism/>
- 24) Baker McKainze, Neil O’Flaherty, Jur Strobous, “FTC and defective advertising claims regardingstemcellTheraphy.”<https://www.lexology.com/library/detail.aspx?g=fb2a23d7-ad10-42ac-aa31-ab6b9eb5b974>
- 25) See. Guidance for Industry, Expedited Programs for Regenerative Medicine Therapies for Serious Conditions. The request for RMAT designation must be made either concurrently with submission of an Investigational New Drug application (IND) or as an amendment to an existing IND. We will not grant a RMAT designation if an IND is on hold or is placed on hold during the designation review. <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/regenerative-medicine-advanced-therapy-designation> visited on 21-04-2020
- 26) “FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review”
- 27) Frame work for the Regulation for Regenerative Medicine products, <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/framework-regulation-regenerative-medicine-products>. visited on 11-04-2020
- 28) Knoepfler P. Stem Cells: An Insider’s Guide. Singapore: World Scientific Publishing Co. Pte. Ltd.; 2013
- 29) FDA News release May 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-puts-company-notice-marketing-unapproved-stem-cell-products-treating-serious-conditions> visited on 21-04-2020.
- 30) Ben Hang Lee et al.v.Human Biostar,Inc. 2012
- 31) Mary A. Chirba & Stephanie Garfield, FDA Oversight of Autologous Stem Cell Therapies: Legitimate Regulation of Drugs and Devices or Groundless Interference with the Practice of Medicine, 7 J. HEALTH & BIOMED. L. 233, 234 (2011).
- 32) Katherine Drabiak-Syed, Challenging the FDA’s Authority to Regulate Autologous Adult Stem Cells for Therapeutic Use: Celltex Therapeutics’ Partnership with RNL Bio, Substantial Medical Risks, and the Implications of United States v. Regenerative Sciences, 23 Health Matrix 493 (2013).
- 33) Adrienne Biddings, Policy Adviser, Google ads help <https://support.google.com/google-ads/answer/9475042?hl=en>. visited on 21-04-2020

- 34) 6th September 2019, ISSCR <https://www.isscr.org/news-publicationsss/isscr-news-articles/article-listing/2019/09/06/isscr-applauds-google-s-new-policy-banning-ads-from-unproven-clinics>.
- 35) FDA -<https://www.fda.gov/media/119936/download>” visited on 1-07-2020
- 36) National stem cell research guidelines 2017.
- 37) ASCI bans 177 ads, 23rd September 2013. <https://www.moneylife.in/article/asci-bans-177-ads-including-nivea-loreal-dabur-pureit-kent-ro-in-july/34665.html> visited on 22-09-2020.
- 38) Id.
- 39) Neetu Chandra sharma, stem cell clinics advertising treatment of incurable disease under government scanner, Business today, March 15 2015. <https://www.businesstoday.in/sectors/pharma/stem-cell-clinics-come-under-health-ministry-scanner/story/217175.html> visited on 22-09-2020
- 40) ASCI upheld complaints against 137 advertisements in October 2019, Best Information Bureau, Delhi , January 14 2020. <https://bestmediainfo.com/2020/01/asci-upheld-complaints-against-137-advertisements-in-october-2019/> visited on 22-09-2020.
- 41) Niti Ayog Achievements in the year 2018-2019 <https://niti.gov.in/verticals/health-and-nutrition/achievements-in-the-year-2018-19> visited on 21-09-2020.
- 42) PR/1435/2016- national consumer redressal Commission
- 43) CC 15/527/- District consumer redressal Commission
- 44) March 20, 2020 News on AIR <http://newsonair.com/Main-News-Details.aspx?id=383425>visited on 21-09-2020.
- 45) Suraksha p “ centre steps up to debunk myths about stem therapy” , Deccan Herald Bengaluru 29/12/2020. <https://www.deccanherald.com/state/centre-steps-up-to-debunk-myths-about-stem-cell-therapy-789550.html> visited on 21-09-2020.
- 46) Chinese patent Application no.CN201080053627”.