INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed JournalMulti Disciplinary
Peer Reviewed Edition :

www.ijlra.com

 ISSN: 2582-6433

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ISSN: 2582-6433

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Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship.He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi.Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi.He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ISSN: 2582-6433

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ISSN: 2582-6433

CRITIQUE ON REGULATION OF STEM CELL RESEARCH IN INDIA WITH RESPECT TO THE EXISTING VACUUM OF GOVERNANCE

AUTHORED BY: SHRUTHI SATISH
Affiliation: Christ (Deemed to be University), Bengaluru
Educational Qualification: 3rd Year, BBA LLB (Hons)

ABSTRACT

Stem Cell Research (SCR) as defined by the Department of Biotechnology (India), is the usage of "*the ability of stem cells to self-renew and give rise to subsequent generations with variable degrees of differentiation capacities, offers significant potential for generation of tissues that can potentially replace diseased and damaged areas in the body, with minimal risk of rejection and side effects*". In India, there is a growing trend of stem cell therapy despite limited scientific evidence supporting its effectiveness and safety. These treatments are considered experimental because they have not undergone rigorous clinical trials. The landscape consists of multiple research guidelines trying to regulate SCR. However, this paper draws attention to the jurisdictional issues that result from the abundance of regulatory bodies and laws when therapies are made available on the private market apart from clinical trials. Although legislative laws have been reinforced, their application is still inadequate and does not adhere to the standards set by professional codes and medical legislation. The author's goal is to demonstrate how the concept of a governance vacuum has to be reconsidered in light of the growing threat to the right to healthcare posed by for-profit medical procedures and a rise in so-called stem cell tourism attracting many patients from the West. The Indian Council of Medical Research and the Department of Biotechnology have released 76 pages of guidelines titled "Guidelines for Stem Cell Research and Therapy," which outline general ethical guidelines for research and procedures for evaluating stem cell activity. However, it has little legal weight because the intricacies of the Indian stem cell industry are not reflected in the intricacy of laws and regulations. Finally, it is argued that this vacuum includes a variety of political injustices that influence healthcare delivery and governance, and these issues are essential to discussions about the governance of biomedical research.

ISSN: 2582-6433

Keywords: Stem Cell Research, Guidelines, Vacuum, Governance, Regulatory Authority

INTRODUCTION

India is rapidly becoming established as a major player in the stem cell sector wherein stem cell therapy is being billed as the next panacea for all ills.[1] However, concerns have been raised about the use of unproven stem cell therapies and the exploitation of donors. Existing regulatory frameworks for the donation, procurement, processing and preservation of cells and tissues are often based on the so-called 'conventional pharmaceutical paradigm', which, considering the distinct features of stem cells, introduces obstacles with respect to the safety and efficacy of stem cell lines which are very different from other pharmaceutical products.[2] In addition to the ethical issues that surround SCR, this research paper delves into the regulatory patchwork regarding the stringency and extent of oversight of clinical application of stem cell products giving rise to "unproven" stem cell therapies. The author also tries to shed light on the implications of the recent regulatory developments while analysing the potential impact of these governance gaps and regulatory ambiguities on the ethical conduct, safety, and scientific integrity of SCR. The author has relied on a qualitative study of document in different media such as news & opinion, scientific literature, and policy reports involving key stakeholders. These documents included news items on stem cell activities published between 2001 and 2020 in leading newspapers available on the internet (Times of India, The Hindu, The Indian Express) and official documents related to stem cell research and medical governance published by government bodies, and articles published in international journals on stem cells in India (Nature, Science, Indian Journal of Medical Ethics). In addition to providing insights into the perspectives of Indian medical professionals on stem cell research and regulation, these articles were also updated to include recent case laws related to stem cell therapy and medical negligence, ensuring that the information presented is up-to-date and reflects the latest developments in the field within the Indian media (*Dr. Bishnu Pada Biswas & Anr. V. UoI & Ors.*[3], *Deepak Khosla v. UoI & Anr.*[4]).

[1]Mittal S, Stem Cell Research: The India Perspective, Perspectives in Clinical Research 2013 Jan-Mar, 4(1); 105-107
[2] Isasi R, Knoppers BM. From banking to international governance: Fostering innovation in stem cell research. Stem Cells Int 2011;498132:1-8 [http://dx.doi. org/10.4061/2011/498132].
[3] 2018 SCC OnLine Cal 11792
[4] 2019 SCC OnLine Del 8857

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THEORETICAL BACKGROUND

SCR mainly utilizes two forms of stem cells- embryonic stem cells and adult stem cells.

I] Fetal Personhood

As of present, one of the ways by which researchers develop stem cell lines is by extracting cells from pre-implantation embryo approximately five days after fertilization, destroying the embryo.[5] To deal with the question of whether embryos have legal rights, we first turn to the abortion rulings of the United States Supreme Court, specifically that of Roe v. Wade (1973).[6] The Court held that personhood could not be granted to a foetus before "viability" (at 24 weeks of gestation). The 1979 Ethics Advisory Board of the (then) Department of Health, Education, and Welfare declared that the human embryo is "entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons." In the present scenario, with the overturning of Roe, the question of unborn persons being legal personalities are of large controversy and debate.

In India, the interests of embryos have been recognized under various statutes such as the Medical Termination of Pregnancy Act (1971), Preconception and Prenatal Diagnostic Techniques (Prohibition of Sex Selection) Act of 1994 and the Indian Penal Code (1860). Therefore, there is a grant to the rights of an unborn child. But the question of what happens to these rights, when the creation of embryos is explicitly for harvesting of stem cells remains unanswered. Afterall, the human germ is not just a mass of cells but an entity disputing the path of evolution.[7]

The ambiguity arises from the fact that the criteria for determining the death of a developing human before the onset of neural development does not exist.[8] Since the zygote is genetically identical to the embryo, which is also identical to the foetus, and by extension, identical to the baby, the beginning of personhood terminates at the 'paradox of heap' (Sorites Paradox- if a grain is taken away from a heap of sand one by one, at what point will it no longer be considered a heap). Jurisprudentially, there is a need to protect nascent human life without hindering the advances of science and innovation.[9]

[5] NAT'L ACADEMIES, UNDERSTANDING STEM CELLS 4-5 (2006), available at http://dels.nas.edu/ dels/rpt briefs/UnderstandingStem Cells.pdf
[6] 410 US 113 (1973)
[7] Rinkevich B, Germ Cell Parasitism as an Ecological and Evolutionary Puzzle: Hitchhiking with Positively Selected Genotypes, Oikos, Vol. 96, No. 1, Jan 2002, pp. 25-30
[8] Lawry D. et al, Embryonic death and the creation of human embryonic stem cells, J Clin Invest. 2004 Nov 1; 114(9): 1184–1186. doi: 10.1172/JCI23065 PMCID: PMC524233 PMID: 15520846
[9] Bernard Lo, Ethical Issues in Stem Cell Research, 14th April 2009, National Library of Medicine, Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726839/

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II] The Adult Human

Besides, totipotent embryonic cells, adult stem cells are also isolated as they help regenerate tissues for renewal and damage repair.[10] Ever since the Nuremburg Code, informed consent has been regarded as a basic requirement for research with human subjects. Donors of stem cells must go through the process consensually in line with conventions on human rights and biomedicine. Religious theology of most major religions takes a positive outlook at this practice. As per the Christian doctrine's, the human, is a psychosomatic unit capable of exercising their own will by the grace of God. The Orthodox Church considers that God during the creation of the human being gave him all the necessary conditions to develop his abilities to exercise for good. This means that man has acquired a specific divine quality and every scientific achievement is a consequence of this. Yet, they do raise objections against therapies when derived from embryonic cells.[11]

In the Islamic religion, the Quran says the foetus acquires psyche and image at the fourth month of pregnancy and so SCR is not acceptable for embryos who have not yet become complete beings.[12] Buddhism[13] recognizes the need to use stem cells if it helps heal and improve the lives of patients while in Hinduism, the ruination of foetus is frowned upon. Nevertheless, there is no official position on SCR in Hindu scriptures.

III] The Research-in-Itself

In totality, SCR continues to be a grey area in terms of whether there is a violation of the principal of beneficence and human dignity. Nonetheless, the duty to heal the sick cannot override the moral imperative to treat human beings as subjects and not objects. The aforementioned theories tell us why regulation is crucial for scientific integrity, consistency, and standardization of stem cell research. There is a need for a remarkably stringent regulatory body that has the mandate and intent to regulate research and protect patients/donors which is currently missing in India.

LEGISLATIONS AND THEIR LACUNAE

I] Global Standpoint

[10] Pessina A et al, The key role of adult stem cells: therapeutic perspectives, Curr Med Res Opin, 2006 Nov;22(11):2287-300., doi: 10.1185/030079906X148517.

[11]Charitos A. et al, "Stem Cells: A Historical Review about Biological, Religious, and Ethical Issues", Stem Cells International, vol. 2021, Article ID 9978837, 11 pages, 2021. https://doi.org/10.1155/2021/9978837

[12] Farkhani E. & Golchini H., Analysis of the use of stem cells from the Jurisprudence and Islamic law, UCT JOURNAL OF SOCIAL SCIENCE AND HUMANITIES RESEARCH 2016(01) Available online at http://journals.researchub.org

[13] Promta S, **Human** Cloning & Embryonic Stem Cell Research: A View from Theravada Buddhist Morality, *Eubios Journal of Asian and International Bioethics* 14 (2004), 197-199.

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Legislation on cell therapy in Europe is based on three directives that define cell therapy products as clinical products, describes the requirements for approval of clinical trials, and establishes the standard quality of procedures relating to human tissues and cells. While some countries have some to no regulations in this field, many others face a complete ban such as France, Austria, Finland, and Portugal. In Germany, derivation of embryonic stem cell lines is prohibited by law although there are projects that have received approval from Germany's main research granting body, DFG.[14]

In South Africa, the Human Tissue Act[15] primarily deals with embryo research. Though it has been enacted, it has not yet been enforced by the president. Japan, despite not having formal guidelines for stem cell research, the Council for Science and Technology Policy voted in favour of continuance of research for therapeutic purposes attracting an investment of US$1 billion for regenerative medicine. The US federal law places some restrictions on the use of embryonic stem cells but has been pro-research in terms of funding. Canadian Institutes of Health Research lays down extensive guidelines for 'Human Pluripotent Stem Cell Research' and sets up a National Embryonic Stem Cell Registry. Australia has been partially supportive while New Zealand restricts stem cell research.[16]

Various international bodies have also published non-binding codes of practice and guidelines to cover stem cell research.[17] For instance, the International Society for Stem Cell Research (ISSCR) is an independent, global, non-profit that was established in 2002 and promotes excellence in stem cell science and its applications to human health. It has formulated guidelines (non-binding code) to "address the international diversity of cultural, political, legal, and ethical issues associated with stem cell research and its translation to medicine."[18] These guidelines are an international benchmark for scientists, regulators, funders, physicians, and members of the public, including patients.

However, regulators throughout the world are not just worried about India. For example, litigation concerning the promotion and provision of untested stem cell treatments has been observed in the United States, the nation that gave rise to the formalised debate on medical ethics. The

[14] Basu S., (10 June 2006) "Regulating stem cell research in India: Wedding the public to the policy", Vol. 90, No. 11, pp. 1476, Current Science Association
[15] Human Tissue Act (No. 65 of 1983), 20th May 1983
[16] Ralston, Michelle (July 17, 2008). "Stem Cell Research Around the World". *Pew Forum on Religion & Public Life*. Pew Research Center. Archived from the original on November 9, 2008.
[17] George B., (Jul-Sep 2011), "Regulations and guidelines governing stem cell-based products: Clinical considerations", doi: 10.4103/2229-3485.83228, PMCID: PMC3159216, PMID: 21897884, Perspectives in Clinical Research
[18] https://www.isscr.org/about

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emergence has also been noted in China, Hungary, Russia, Europe, and Thailand.[19] While the main focus of the paper is India, it has to be understood within the wider global political economy of stem cell activity.

II] National Standpoint

The conflict between the necessity of promoting new technologies and the requirement to regulate them is a major issue for this kind of government. The question of how these new objects of governance is created and organised arises when they are shown to require action.

Examining formal laws and rules alone is insufficient; equally important are professional standards of conduct that have taken on legal characteristics even though they have never been publicly stated as such. For laws to have social meaning "they must become embedded in people's imaginations and understandings, and worked out in their practical dealings with one another"[20] The flip side to that is some laws may exist only in the rulebooks but not practice, creating an implementation gap. This results in compliance, non-compliance, and sometimes even over-compliance with the law by different actors. Yet, the fact remains that guidelines cannot compel action in the ways laws ostensibly can.[21]

The Indian stem cell sector garnered much social interest in the mid-2000s as several studies showed there was a lack of statutory regulation of stem cell activities. Thereafter, the central document regulating SCR in India is the National Stem Cell Guidelines[22] jointly prepared by the Indian Council of Medical Research and Department of Biotechnology. It was drafted in 2007 and then subsequently amended in 2013 & 2017. The most dramatic change that is noticed is limited to only the title. In 2007, the document was titled "Guidelines for Stem Cell Research and Therapy," with an emphasis on the therapy aspect. However, by 2013, the title was changed to "Guidelines for Stem Cell Research" to clarify that stem cell therapy was not permitted. The authors of the 2013 document clarified that stem cell therapy is prohibited, emphasizing the need for guidelines to regulate its use. They reiterated the crucial aspect of conducting clinical stem cell applications only within authorized trials, a requirement already mentioned in the 2007 version but seemingly overlooked by those involved in unauthorized practices. The document's

[19] Verginer, L., Riccaboni, M. Stem cell legislation and its impact on the geographic preferences of stem cell researchers. *Eurasian Bus Rev* **11**, 163–189 (2021). Available at: https://doi.org/10.1007/s40821-021-00182-0
[20] Jasanoff, S. 2011b. "Introduction: Rewriting Life, Reframing Rights." In Reframing Rights: Bioconstitutionalism in the Genetic Age, edited by S. Jasanoff, 1–27. Cambridge: MIT Press
[21] Shashank Shekhar Tiwari, *The Ethics and Governance of Stem Cell Clinical Research in India (2013*) (unpublished Ph.D. thesis, University of Nottingham), available at http://eprints.nottingham.ac.uk/14585/
[22] Indian Council of Medical Research & Department of Biotechnology, National Guidelines for Stem Cell Research (2017)

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guiding principle is to prevent the premature commercialization of unproven stem cell therapies while fostering scientific knowledge grounded in sound research principles and addressing ethical concerns.

The latest edition is much more stringent compared to its earlier form as it omits the word "therapy" from the title as stem cells are not a standard of care and hence there cannot be guidelines for therapy until efficacy is proven (exception is provided for hematopoietic stem cells as they are already established as a standard of medical care). Despite a comprehensive document, there is no statutory backing for these regulations as the ICMR is a research institution under the Ministry of Health and Family Welfare & its role is limited to "formulation, coordination and promotion of biomedical research" while the DBT is under the Ministry of Science and Technology who aims to promote biotechnology in India. Neither body possess enforcement abilities over clinics and hospitals. So, the ICMR can only provide advice and easily overlooks how the guidelines are being ignored in practice.

Today, as per public records, the Department of Health Research- Indian Council of Medical Research (DHR-ICMR) has been supporting biomedical research specifically for "basic stem cell biology, Cancer stem cell, Translational research and Generation of induced pluripotent stem cells (iPSC), open ended investigator-initiated ad-hoc projects and fellowships"[23] for the last twenty years. Between 2017 to 2020, the Council of Scientific & Industrial Research (CSIR), through its constituent laboratories namely CSIR- Institute of Genomics and Integrative Biology (CSIR-IGIB), New Delhi and CSIR- Institute of Chemical Biology (CSIR-IICB), Kolkata even undertook a 'Sickle-Cell Anaemia' mission. The aim was to provide for prevention and care for people with the disease by using stem-cell derivatives.[24]

To further push SCR into the mainstream, the government even constituted a Stem Cell Task Force in 2003. It's main purpose was to plan, execute, monitor, and evaluate protocols. Additionally, there was also a proposal for the formulation of a "stem cell priority fund" that would collaborate with the ICMR, Department of Science and Technology, and the Defence Research and Development Organization.[25]

Consequently in 2008, the Central Drugs Standard Control Organization (CDSCO) furnished a guiding document on requirement of approvals for biotechnological/biological products which

[23] Press Release; Ministry of Health and Family Welfare, 30th July 2021, Available at: https://pib.gov.in/PressReleasePage.aspx?PRID=1740749

[24] National Sickle Cell Anaemia Elimination Mission, https://sickle.nhm.gov.in/home/about#:~:text=The%20mission%20aims%20to%20cover,in%20three%20and%20half%20years.

[25] Lahiry S. et al., *The National Guidelines for Stem Cell Research (2017): What academicians need to know?*, 0ct 2019, National Library of Medicine, Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6801994/

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includes stem-cell products and derivatives. Later in 2010, it also formed the Cell Biology Based Therapeutic Drug Evaluation Committee (CBBTDEC) to review cell therapy based clinical trials. The procedure is such that the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) must mandatorily approve said clinical trials, then be registered with the Institutional Committee for Stem Cell Research (ICSCR) and Institutional Ethics Committee (IEC). The clinical trials can only be undertaken Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) certified facilities.

Another legislation of significance is the Drugs and Cosmetics Act[26] of 1940, defines stem cells and their derivatives under the definition of 'drug' and classify them as 'Investigational New Drug' or 'Investigational New Entity' when used in clinical application. Furthermore, the Drugs and Magical Remedies (The Objectionable Advertisements) Act[27] of 1954 prohibits all clinics and hospitals from advertising remedies alleged to possess magic qualities including matters of stem cell treatment. However, there have been instances of blatant flouting of these rules by medical institutions who offer "stem cell treatment" for different disorders under the guise of clinical trials.

The introduction of New Drugs and Clinical Trials Rules[28] in 2019 expands the scope of "new drugs" to include stem cell-based products Sec. 2 (w) (v). The rules apply to and regulate all new investigational new drugs for human use, clinical trials, bioequivalence studies, bioavailability studies and ethics Committees. Yet, it does not provide a definition for what constitutes stem cell derived product.

When read together, the present framework presents multiple bodies from different ministries having several legislations trying to bring governance around stem cell activities. It is pertinent to note there is no permanent regulatory body to keep the field under active review.

III] The Uneven Political Playing Field

While the scientific promises of SCR have been fairly accounted for, its limitations in the present form also need to be noted. Evangelical advertising and over promises have clouded the judgment of many. For instance, the controlled trial of embryonic stem cells to cure Parkinson's disease was a failure and even worsened the disease.[29] SCR's potentiality brings hope to many afflicted

[26] Drugs and Cosmetics Act, No. 23 of 1940, Acts of Parliament, 1940 (India)
[27] Drugs and Magical Remedies (Objectionable Advertisements) Act, No. 21 of 1954, Acts of Parliament, 1954 (India)
[28] New Drugs and Clinical Trials Rules, Ministry of Health and Family Welfare, Government of India, G.S.R. 227(E) (Mar. 19, 2019).
[29] Spencer, et al., Unilateral Transplantation of Human Fetal Mesenpephalic Tissue into the Caudate Nucleus of Patients with Parkinson's Disease, 327 NEW ENG. J. MED. 1541, 1548 (1992).

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by incurable disorders. But the truth remains that the progress in terms of knowledge and clinical application is largely lacking. The mindset of the average citizen however, does not account for the harm being caused by the unrealistic expectations vis-à-vis the actual reality.

This is why in a democratic society, any sort of technological innovations needs to be subjected to some regulatory machinery i.e., legislations & regulation. Ultimately the limitation may cause hindrances in the use of the innovation but it would be for the common good. Public policy has to carefully balance scientific knowledge, ethics, and rights of every individual. The principles of liberty of choice and social justice plays an important role as the legislature must protect the rights of freedom, choice, privacy, and conscience. It is the choice of every person to use or not use a new technology. If he feels a policy to be morally reprehensible, he is free to object and push for amending the policy through the legal recourses available to him.[30]

Such a power cannot be left to private entities or individual persons for history tells us of the varying moral inclinations of persons. The pursuit of knowledge, taking place for the benefit of humanity, means placing public good at the mercy of a body experts and entrepreneurs. Although, legality as conferred by this group of people does not confer a moral status upon SCR anymore than it confers moral status upon abortion or euthanasia.[31]

Regardless of the public policy chosen, it must be fair in formulation and implementation. This entails meeting the standards of both commutative and distributive justice. The focus is always upon legislating fairly which involves adherence to the principles of justice, which ensures that each person receives what they deserve (treating equals equally and unequals unequally). The principles apply to individuals in the form of commutative justice and to societal arrangements as seen in distributive justice.

Another concern is the ability to afford stem cell treatments. The affair because of its high costs are denied to the poorer members of the society. The economically weaker section is left out from purchasing custom-tailored stem cells. So, if the biotechnology is to become truly effective, some evolution of social justice or economic justice, must also be incorporated into the field. Monopoly is already an issue of the present. Geron of Menlo Park (California) owns the commercial rights to the Technology that produced 'Dolly', the first cloned sheep as well as telomerase.[32] But telomerase is a vital enzyme in studying cancer cells. This brings up the crucial issue of determining the extent of property rights over biological materials, which intersects with both

[30] Hengstschlager M., Embryoid research calls for reassessment of legal regulations, 19th June 2021, Stem Cell Research & Therapy, Available at: https://stemcellres.biomedcentral.com/articles/10.1186/s13287-021-02442-2

[31] Pellegrino E., Balancing Science, Ethics, and Politics: Stem Cell Research, A Paradigm Case, Journal of Contemporary Helaht Law & Policy, 2002, Vol. 18, Issue 3, Available at: https://scholarship.law.edu/cgi/viewcontent.cgi?article=1202&context=jchlp

[32] Andre Pollack, The Promise of Selling Stem Cells, N.Y. TIMES, Aug. 26, 2001

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individual and social justice concerns. It prompts us to consider how much control should be exerted for the public good versus what should be left to market forces. In nations where healthcare is commodified, there's (unfortunately) a significant risk of extending commodification to human cells. Money, profit, and ethics often find themselves at odds. Thereafter, the outcomes of our collective discussions will affect everyone in society, either as victims or beneficiaries. We must strive for morally upright, scientifically accurate, and politically fair decisions.

CONCLUSION

In conclusion, the discourse surrounding stem cell research in India is marked by a perceptible vacuum in governance and ambiguous regulatory mechanisms. Despite the remarkable potential of this rapidly evolving field, the lack of clear-cut jurisdictional boundaries and well-defined policies is a significant impediment. As elucidated in this paper, several studies have highlighted these issues, pointing towards a need for comprehensive reforms.

The presence of this governance vacuum has resulted in a climate of uncertainty, potentially stagnating the progress of stem cell research and therapy in India. This regulatory lacuna, coupled with lax implementation of existing guidelines, further exacerbates the situation. The need of the hour is a robust and transparent regulatory framework that strikes a balance between facilitating research and ensuring ethical and safe practices.

As India, along with other nations such as China, Russia, and Hungary ventures into the bioethical vacuum of stem cell research, it is imperative to develop a governance structure that is responsive to the evolving needs of this dynamic field. Only then can the full potential of stem cell therapies be realized, paving the way for revolutionary advancements in medical science.