ISSN: 2582 - 2942

LEX FORTI

LEGAL JOURNAL

VOL- I ISSUE- VI

AUGUST 2020

ISSN: 2582 - 2942

DISCLAIMER

ISSN: 2582 - 2942

EDITORIAL BOARD

ISSN: 2582 - 2942

EDITORIAL BOARD

ISSN: 2582 - 2942

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Understanding Therapeutic Cloning: An analysis of its benefits, issues and Legal Framework

Nishtha Pant

INTRODUCTION

Biotechnology is a major breakthrough and revolutionary concept in the present world. In order to get an insight into the field of biotechnology, it is of paramount significance to firstly understand its meaning. In the year 1993, *Convention on Biological Diversity (CBD)* defined 'Biotechnology' as ***'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.'*** The most fascinating aspect of Biotech industry is that it is enveloped in a futuristic and innovative approach which has put it in a high pedestal in myriad facets of life. Consequently, biotechnology finds application in various fields such as food production, industry, environmental protection and health care.[1]

Cloning, is one such trend of biotechnology, which has the potential to enhance beauty and creativity of this field. In this project, the researcher has dealt with the concept of 'cloning' which is one of the most fascinating and controversial issues in the present times. The topic has been dealt firstly by introducing the meaning, historical background and types of cloning. The introductory part is followed by a discussion on resultant benefits, concerns, international legal framework and national laws wherein the researcher has primarily focused on therapeutic cloning alone. Since reproductive cloning is prohibited around the world, at least as of now, the researcher has based the project on therapeutic cloning primarily and hasn't touched upon reproductive cloning in detail.

CLONING – ITS MEANING

Though cloning gained popularity in the recent times, it has been a common practise in the field of horticulture since ancient times. In those times, several kinds of plants used to be cloned simply by obtaining cuttings of their leaves, stems, or roots and replanting them.[2] In the year 1903, a famous plant physiologist Herbert J. Webber coined the term **"clone"** from the Greek **klon,** to describe the process by which new plants were grown by using cuttings, bulbs or buds.[3] In subsequent decades, as per present scientific terminology, the noun clone refers to each individual molecule, cell, or organism propagated from the original ancestor or template.[4] As far as biomedical research is concerned is concerned, cloning means '***the duplication of any kind of***

[1] M.R. Das, 'Biotechnology in the 21st Century'(2001) 51(4) DSJ <https://publications.drdo.gov.in/ojs/index.php/dsj/article/download/2246/1204> accessed 29 March 2020

[2] < https://www.merriam-webster.com/dictionary/cloneaccessed> 29 March 2020

[3] Joe Palca, Interview with Professor Howard Markel (University of Michigan) (March 11, 2011)

[4] 'The threat of Human Cloning, Part One -Scientific and Historical Background'(2015) The New Atlantis- A journal of Technology and Society< https://www.thenewatlantis.com/> accessed 30 March 2020.

biological material for scientific study, such as a piece of DNA or an individual cell.'[5] In other words, it can be said that cloning is the process by which a replication of a biological unit (such as a DNA sequence, cell, or organism) is done, more specifically with the help of biotechnological methods.

HISTORICAL TIMELINE OF CLONING

- It was in the year 1928 when the first ever nuclear transfer experiment was undertaken by a German embryologist, Hansa Spemann wherein he experimented with transferring salamander embryonic cell nuclei into egg cells. Later when he retired, in 1938 he put forth a "fantastical experiment" to transfer one cell's nucleus into an enucleated egg. His proposed experiment, which was proposed by him at a time when nuclear transplantations was not a popular concept, now forms the basis of the method of cloning. [6]
- In the year1952, Robert Briggs and Thomas J. King produced tadpoles by injecting blastula nuclei singly into eggs of the Northern Leopard Frog from which the nucleus had been removed.[7]
- It was in July 1996 that a major breakthrough happened in the field of cloning since it was the first time when an organism i.e. Dolly the sheep was cloned from the adult stem cells and not the embryonic stem cells. Ian Wilmut generated Dolly, with the help of nuclear transfer wherein an enucleated embryo and a nucleus of a differentiated cell were involved. This technique, when it was later refined came to be known as somatic cell nuclear transfer (SCNT).[8]
- The SCNT technique highlighted major advancement in the field of cloning since it aided the creation of a genetically identical clone of an already grown sheep. It, therefore, indicated towards the possibility that DNA in differentiated somatic (body) cells could be reprogrammed into undifferentiated cells at embryonic stage, thereby reinstating the pluripotency wherein such undifferentiated embryonic cells have the ability to develop into different forms of body cells which make up a complete organism. With this extraordinary scientific development that the DNA of adult cells (Somatic cells) could be again reverted to

[5] Michael Rugnetta, 'Cloning', *Encyclopaedia Britannica* <https://www.britannica.com/science/cloning> accessed 1 April 2020

[6]KarenWellner, 'Hans Spemann (1869-1941)', *The Embryo project Encyclopaedia*<https://embryo.asu.edu/pages/hans-spemann-1869-1941> accessed 2 April 2020

[7]Marie A. Di Berardino and Robert G. Mckinnell , 'The Pathway to Animal Cloning and Beyond Robert Briggs (1911–1983) and Thomas J. King (1921–2000)',(2004)301(1) <https://onlinelibrary.wiley.com/doi/abs/10.1002/jez.a.20045accessed > 3 April 2020

[8]Kre{imir Paveli} , 'Arguments for Human Therapeutic Cloning' (2004)IV (1) BJBMS IV (1) <https://www.bjbms.org/ojs/index.php/bjbms/article/download/3454/1011>accessed 5 April 2020

its pluripotent state, a new horizon opened up which significantly impacted research with respect to therapeutic cloning and also the development of stem cell therapies.[9]

TYPES OF CLONING

THERAPEUTIC CLONING

Meaning: The Merriam Webster Dictionary defines the term 'therapeutic' as '***of or relating to the treatment of disease or disorders by remedial agents or methods'.*** Therefore, therapeutic cloning means cloning in relation to treatment of disease or disorders. 'Therapeutic cloning' uses experimental techniques to clone tissues or stem cells for purposes other than reproduction such as research, embryonic stem cell lines, or even creation of organs for transplantation.[10]

Process: In therapeutic cloning, a nucleus from a somatic cell is taken out and is put inside an enucleated egg (i.e. an egg cell from which nucleus is removed). Consequently, a zygote is formed interestingly even if no independent sperm and egg have come together. Next, the egg is made to undergo chemical process or electronic shock to facilitate cell division. Eventually, embryonic stem cells, also known as inner mass of cell is formed in the blastocyst stage.

Purpose: Later on, these stem cells obtained via SCNT can be harvested and serve an important role in experiments undertaken to understand diseases and to develop new treatments. [11] It can be clearly seen that in case of therapeutic cloning, the cloned embryos are created with the sole objective to extract stem cells from them. In no way does therapeutic cloning intends to implant the embryo in the uterus.[12]

REPRODUCTIVE CLONING

Meaning*: 'Reproductive cloning'* is defined as the ***'use of somatic cell nuclear transfer (SCNT) or other technologies to create offspring with the shared genomic material of the original person.'***[13] In simple words**,** reproductive cloning is the process by which genetically identical organisms are created. The reproductive cloning differs from therapeutic cloning in the way that while former is used to clone an entire organism, latter is only used to clone stem cells.

Process: As far as reproductive cloning is concerned; it can be done by two methods wherein both methods require that the embryo be implanted in the uterus. Consequently, a normal period

[9]Rugnetta (n5)

[10] 'Human somatic cell nuclear transfer and cloning', (2012) 98(4)ASRM <https://www.fertstert.org/article/S0015-0282(12)00698-X/fulltext>accessed> 23 April 2020

[11] Alina Bradford ,'Facts About Cloning' (*Live Science Contributor,* 2 March 2017) <https://www.livescience.com/58079-cloning-facts.html> accessed 2 April 2020

[12] Rugnetta(n5)

[13] (n10)

of pregnancy continues till the cloned organism having the identical genetic makeup is born. The two methods are as follows:

• **Cloning using somatic cell nuclear transfer (SCNT) :** This procedure is same as that for the purpose of therapeutic cloning wherein a nucleus taken from a somatic cell of the person who is to be cloned is injected into an enucleated egg. Once stimulation is provided to the cell, cell division begins resulting into formation of a blastocyst, or preimplantation embryo. The blastocyst is then transferred to the womb of an animal/surrogate mother wherein embryo continues to grow as in case of a normal pregnancy.

• **Cloning by embryo splitting**: In this process, there is in vitro union of a sperm and an egg to generate a zygote. Once the zygote has reached the state where four identical cells have formed, then these cells can be separated and allowed to develop into separate but identical blastocysts, which can then be implanted in a uterus. [14]

Purpose: Unlike therapeutic cloning, purpose of reproductive cloning is to clone a complete organism. For this purpose, the blastocyst is not used for the extraction of stem cells instead it is implanted in the womb itself. The reproductive cloning may have manifold purposes for e.g. dealing with infertility issues, avoiding transfer of genetic risk, replicating individuals of high-quality traits so that society can benefit from them etc.

BENEFITS OF THERAPEUTIC CLONING

Therapeutic cloning has extraordinary potential to revolutionise the field of medicine. There are multiple ways in which therapeutic cloning can serve a prominent role in the field of medicine by discovering new diseases by way of research, by developing new and effective treatments for chronic diseases, or by using the extracted stem cells for repairing or replacing damaged organs or tissues and so on. [15] Few of the benefits have been listed below:

CLONING TO MAKE STEM CELLS:

Stem cells continue to be made, maintained and repaired naturally in the body throughout the lives of an organism. Although this process of stem cells is a natural one, another alternative to the natural process is that these stem cells can be manipulated so as to repair damaged or diseased organs and tissues. Many researchers around the world agree to look at cloning as a way of creating embryonic stem cells. The importance of these cells has been recognized in the scientific literature

[14] *Scientific and Medical Aspects of Human Reproductive Cloning (National* Academies Press (US)2002). < https://www.nap.edu/catalog/10285/scientific-and-medical-aspects-of-human-reproductive-cloning > accessed 21 April 2020

[15]Rugnetta(n5)

and by the National Institute of Health (US) as having important biological properties.[16] Stem cells created via SCNT in therapeutic cloning have immense potential to be used for medical purposes as they can be turned into any type of cell in the body.[17]

Therapeutic cloning is, therefore, important as it also enhances human's understanding of how stem cells work and develop. Consequently, new treatments or cures for common diseases might also be developed accordingly. In other words, scientists might be able to eventually create stem cell therapies which are peculiar to the concerned patient's medical condition.[18]

Stem cells can also be of huge significance as they can serve as an alternative to screen new drugs and toxins instead of screening tests which is otherwise done on the animals who have a different genetic makeup than the humans. Therefore, this alternative is a more accurate process wherein new medications can be tested on differentiated, specific human cells in a controlled and supervised set-up, before being tested for safety on the human body itself.[19]

APPLICATIONS IN THE FIELD OF REGENERATIVE MEDICINE:

The field of Regenerative medicine is an evolving science with a multidisciplinary approach which applies engineering and life science principles to promote regeneration, healing or replacement of damaged and injured tissues and organs either due to age or disease or other factor so as to restore the normal functioning of the body or organ.[20] It is one such field which can benefit immensely from the advances in the cloning technology more particularly in the form of therapeutic cloning. Since the object of regenerative medicine is to help relieve patients who are suffering due to a disease or injury by restoring the damaged or injured tissue and organs, therapeutic cloning can be of paramount importance in advancing the regenerative medicine.

Applying the techniques of tissue engineering on the '**potentially endless source of versatile cells',** which are formed via SCNT in therapeutic cloning**,** might help in discovery of novel sources of organs for the purpose of transplantation.[21] Consequently, one of the most significant contribution of therapeutic cloning in the field of medicine is growth of organs for purpose of

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[16] Vanessa J. Hall, Petra Stojkovic and Miodrag Stojkovic, 'Using Therapeutic Cloning to Fight Human Disease: A Conundrum or Reality?', (2006) 24STEM CELLS https://stemcellsjournals.onlinelibrary.wiley.com/doi/pdf/10.1634/stemcells.2005-0592> accessed 22 April 2020

[17]University of Utah,' Why Clone?' Genetic Science Learning Center <https://learn.genetics.utah.edu/content/cloning/whyclone/> accessed 29 April 2020

[18] Ian Murnaghan, 'Therapeutic Cloning', (*explorestemcells*, 10 Feb 2020 <http://www.explorestemcells.co.uk/therapeuticcloning.html>accessed 30 March 2020

[19]Department of Science and Technology, *Cloning And Stem Cells-Public Understanding of Biotechnology* (2014) <https://www.pub.ac.za/wp-content/uploads/2015/06/Factsheet-Pub-CloningPRINT2> accessed 25 March 2020

[20] Mao AS, Mooney DJ, 'Regenerative medicine: Current therapies and future directions'(2015)112(47) Proc Natl Acad Sci U S A.

[21] Anthony Atala and Chester J. Koh, Annu, 'Tissue Engineering Applications of Therapeutic Cloning'(2004)6 Rev. Biomed. Eng.< https://www.annualreviews.org/doi/abs/10.1146%2Fannurev.bioeng.6.012204.115707> accessed 29 March 2020

transplantation wherein stem cells to be used have the same genetic makeup as the organ recipient which also overcomes the possibility of immune rejection.

Another application of therapeutic cloning in the field of regenerative medicine is growth of nerve cells. A small growth of nerve cells can have miraculous effects on persons who are either paralyzed from the neck down due to some mishap so much so that transmission of nerve activity from the brain to the rest of the body and vice versa is interrupted.[22] Apart from that therapeutic cloning has the potential to treat Parkinson's disease and its advancement could eventually be even extended for treatment of cortical atrophy resulting from stroke or for Alzheimer's disease.[23] Also, in type 1 diabetes, wherein pancreatic cells fail to produce insulin then stem cells in culture might be turned into insulin producing cells , thereby helping in retaining the normal functioning of the body.[24]

LESS CHANCES OF IMMUNE REJECTION FROM PATIENT:

In therapeutic cloning, there is a nucleus which is taken out of the somatic cell of the patient and that nucleus is injected into an enucleated egg to form a zygote which eventually leads to formation of stem cells. Thus, the stem cells which are generated have the identical genetic makeup to patient to be treated. It is one of the beneficial aspects of therapeutic cloning since the cell incorporated in the person is familiar with the immune system already. Due to already existing compatibility, a lot of complications can be avoided which might arise in the situations wherein heterologous transplants (such as the case in organ donation) has been done.[25]

It has been found that when stem cells are transferred from one person to another for instance, bone marrow transplant then such recipient's immune system generally recognises that such donor organ or stem cell is foreign thereby triggering immune response.[26] Therefore , therapeutic cloning can be of great help since it reduces the chances of immune rejection by the recipient's immune system since the stem cell being incorporated has the same genetic features as the recipient itself.

INCREASED KNOWLEDGE OF DEVELOPMENT AND DIFFERENTIATION:

On a careful study and analysis of stem cells produced in therapeutic cloning, researchers are gradually gaining insight as to how the development of organisms occur from single cells and how the birth defects arise. It is eventually helping them understand as to what signals are to be

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[22]Francisco J. Ayala, 'Cloning humans? Biological, ethical, and social considerations'(2015)112 PNAS< https://www.pnas.org/content/112/29/8879> accessed 1 April 2020

[23] Charlotte Kfoury ,'Therapeutic cloning: promises and issues'(2007)10 MJM https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2323472/ accessed 2 April 2020

[24] (n19)

[25] Aurélie Halsband, 'Research Cloning', (*drze*, December 2019, http://www.drze.de/in-focus/research-cloning/medical-aspects accessed 22 April 2020

[26] (n17)

provided to cells so that they can change their function to another. Consequently, they might learn how to control differentiation of stem cells thereby producing a specific tissue. Once the phenomenon of differentiation is clear, it might help in understanding the abnormalities in differentiation wherein such abnormalities might lead to diseases such as cancer.[27] It might become possible to even detect whether a particular type of cancer arises from a genetic or an epigenetic defect. [28]

INSTANCES OF SUCCESSFUL APPLICATION OF THERAPEUTIC CLONING:

A major breakthrough in the field of Therapeutic Cloning was published by ***Tabar et al. in 2008*** wherein outcome of an experiment on stem cells obtained from a cloned embryo for the treatment of Morbus Parkinson was discussed. In the therapeutical experiment, ***skin cells of mice with Parkinson's disease were used to create cloned embryos.*** Later on, the stem cells from the cloned embryos were extracted and developed into peculiar nerve cells. These were then injected into the donor mice and the mice showed no immune rejection instead it showed signs of relief. However, it is not yet certain as what results would be yielded when the experiment is done with humans. **[29]**

Another successful application related to therapeutic cloning was done by ***Oregon Health and Science University.*** Their researchers succeeded in using cloning to for creation of human embryonic stem cells which paves way for future of developing replacement tissues and the same can help in devising treatments. For the purpose of creating human ESCs, the researchers took the skin cells from an 8-month-old child having a genetic disease and fused those with the donated enucleated eggs in order to human embryos having the identical genetic makeup of the child. It is a great boost in the research field that the scientists were able to get cloned human embryos which survived long enough for stem cell extraction.[30]

CONCERNS WITH RESPECT TO THEARPEUTIC CLONING

MORAL AND ETHICAL ISSUES:

Despite the unfathomable and extraordinary potential of therapeutic cloning, it has always been a subject-matter of debate on the grounds of ethical and moral considerations. The primary questions being-

[27] (n19)
[28] Kfoury(n23)
[29] Halsband(n25)
[30] Andrew Pollack, 'Cloning Is Used to Create Embryonic Stem Cells' *The New York Times* (15 May, 2013 <https://www.nytimes.com/2013/05/16/science/scientists-use-cloning-to-create-embryonic-stem-cells.html> accessed 5 April 2020

- Is it appropriate create and then destruct those embryos for the purpose of therapeutic cloning? or,
- In other words, is it justified to look into an embryo as a commodity and not as having potential to develop into a being?

The opinions are bifurcated in two different dimensions. The individuals or groups who object therapeutic cloning are of the belief therapeutic cloning is immoral and unethical since it deals in production and then the destruction of the embryo which has the potential to breathe and live in the world. It is their argument that this technique is going to change the perception of human life as if it can be moulded or destructed for any purpose.[31] In this way human life is being used as a means to an end. Their arguments are based on the belief that a morally significant human life begins at the conception itself. According to Dawson and Singer, "…it is not logically impossible for a human blastocyst in a laboratory to develop into a person'. Therefore, its not morally and ethically justified to use a potential human life as a means to an end when its possible that it can evolve as a living soul even if probabilities of same seem bleak.[32]

However, there are certain individuals or groups who support therapeutic cloning as they believe that it is completely moral and ethical to heal and liberate those people who are suffering from illness or diseases so that their standard of life can be enhanced. They are of the opinion that therapeutic cloning should be allowed as well as funded just as any kind of therapeutic research. Many of these supporters believe that therapeutic and research cloning should be not only allowed but also publicly funded, similar to other types of disease and therapeutics research. However, many philosophers and policy makers argue that women and couples should not ever be exploited or pressurised for providing eggs or embryos.[33] No doubt human pre- embryos deserve respect. But, as Robert Lanza once pointed that it is not justified to bestow rights and importance on a human embryo as that of a living identity and that too at the expense of suffering of an existing soul- who might be our loved ones and might end up dying because of the so-called moral dilemma.[34] According to McMahan, unlike the late-term embryo, the early embryo is merely an "insentient cluster of cells" which doesn't have the potential to be identified morphologically to a mature organism. He argued that while the latter has a higher mental life and cognitive capacities including conscience, the early embryo is completely devoid of such characteristics. Therefore, it

[31] Rugnetta(n5)
[32] Kfoury(n23)
[33] Rugnetta(n5)
[34] Kre(n8)

seems morally justified to destruct an embryo of lower moral significance as long as it is being used for improving the existing living beings of higher moral status.[35]

3.2 Social issues: The tenable pro-therapeutic cloning arguments might be that therapeutic cloning by treating and relieving the patients from their sufferings can go a long way in improving their standard of living in the given society. Also, as is commonly known, a healthy mind dwells in a healthy body. Therefore, a society full of healthy individuals can be an asset to the growth and development of all and sundry since their potential would then not be undermined by any illness or disease or injury.

While on the other hand, those who are against therapeutic cloning argue that it might adversely impact the already crippling self-esteem of those who are suffering from illnesses like dyslexia, schizophrenia and autism etc. If therapeutic cloning advances medicinal science in such a way that it becomes possible to avoid these diseases or illnesses then it would make them feel that they are different from others and are viewed as liabilities or imperfections in the society.[36]

RELIGIOUS ISSUES:

One of the most prominent religious question pertaining to 'therapeutic cloning' is that how far is it justified to 'play God'? The major argument is that human beings are fallible whose self-interested perspectives and narrow mindset should not defy the supreme power of the divine. Once Paul Ramsey validated his objections by asserting: ***"Men ought not to play God before they learn to be men, and after they have learned to be men, they will not play God."***[37] We humans don't know the repercussions of playing with the nature or the divine powers or will.

The religious issues concerned with therapeutic cloning are also divergent and varied. For instance, some ardently conservative followers of Christianity and others believe that human person-hood starts at conception. Therefore, they believe that a pre-embryo is a human person itself and therapeutic cloning is actually killing a person merely for extraction of stem cells. might actually be causing murder of this person in order to extract its stem cells. On the other hand, there are certain groups who argue that the embryo does not deserve any specific moral consideration as it is simply a cluster of cells with no body parts or brain or consciousness, memory, thoughts, etc. It can be granted human personhood only once it is implanted in a female's womb. There are also those who acknowledge the status of embryo yet argue that the status of embryo becomes more profound only when it develops so in early stage scenario it can be a subject matter of research if

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[35] Kfoury(n23)

[36] Bioethics Advisory Committee Singapore, *Ethical, Legal and Social issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning*(June 2002)

[37] Bernard E. Rollin, 'Keeping up with the Clones: Issues in Human Cloning'(1999)3(1) I. Ethics <https://www.jstor.org/stable/25115600> accessed 6 April 2020

there are potential benefits of the same. Therefore, there is no consensus of the varied religious beliefs with regard to therapeutic cloning.[38]

ECONOMIC OR FINANCIAL ISSUES:

Firstly, there is no clarity as to the financial funding to research involving therapeutic cloning. For instance, even in the country like Us where therapeutic cloning is not per se banned doesn't permit federal funding in experiments involving the 20 cell lines in the NIH (National Institute of Health) registry derived before August 9, 2001. Out of these cell lines which were then approved by Bush, 12 of them died and the remaining no longer remained fruitful for research purposes. Consequently, researchers have to rely on private funding.[39] Therefore, financial roadblock in the field of therapeutic cloning pertaining as to how can public funding be allocated for the purpose of research remains a burning issue.[40]

Secondly, there is an ethical dilemma as to whether eggs(oocyte) which are provided by the women to the researchers should be a subject-matter of financial transaction involving buying and selling. Proponents say that it is of paramount importance to compensate women who donate their eggs for the purpose of research just as the women who give their eggs for fertility purposes are already paid. On the other hand, others believe that this would simply commodify the entire human existence and might even cause exploitation of women simply because they are in dire need for financial assistance. [41]

Last but not the least, since most of the research is carried out by the private commercial clinics, reported successes are not subject to peer review. Consequently, patients might be subjected to financial exploitation as they might be charged exorbitantly for treatments by being given a false hope that they would be cured even if stem cell therapies are only in their developmental stages.[42]

HUMAN RIGHT ISSUES:

FREEDOM OF SCIENCE:

The international instruments evidently discuss the right or freedom pertaining to contributions in scientific research. For instance, UDHR refers to right to share in scientific advancement. While ICESCR (1966) provides that the states must respect 'the freedom indispensable for scientific research. Therefore, advocates of therapeutic cloning believe that associating moral considerations to embryo should not serve as a roadblock to cloning for research purposes.

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[38] https://geneticstherapeutic.weebly.com/societal-issues.html accessed 22 April 2020
[39] Kfoury(n23)
[40] (n36)
[41] Libby Nelson ,'New York State Allows Payment for Egg Donations for Research' *The New York Times* (26June 2009)< https://www.nytimes.com/2009/06/26/nyregion/26stemcell.html?partner=rss&emc=rss> accessed 22 April 2020
[42] https://www.bbc.co.uk/bitesize/guides/zs8y4qt/revision/3 accessed 21 April 2020

RIGHT OF POTENTIAL PATIENTS WHO MAY BENEFIT FROM THERAPEUTIC CLONING:

The ICESCR recognizes the human right 'of everyone' to the enjoyment of the highest attainable standard of health as well as right 'to enjoy the benefits of scientific progress and its applications.' Consequently, many groups, organisations and individuals argue that 'health is a human right, not a commodity or a privilege' and therapeutic cloning research has potential to produce enormous heath benefits'.[43] However , it is also essential that the health benefits must be accessible to everyone regardless of any hierarchy so that human integrity remains intact.

PROTECTING EGG DONORS:

Eggs serve as the foundation of the cloning research. Women undergo rigorous hormonal treatment to produce a large number of eggs in a given cycle. There might be risks as well in several situations.[44] Therefore, several human rights activists argue that women should be given ideal care in the course of donation procedure or even for treatment in case of any adverse situation. Their informed consent must be taken which must be free and voluntary.[45]

INSTANCES OF FAILURE OF THERAPEUTIC CLONING:

In one of the experiments, researchers at Harvard Medical School and McLean Hospital in Belmont, Massachusetts, injected cloned embryonic stem cells into total 25 rats who exhibited symptoms of Parkinson's disease. Out of these, condition of 14 rats improved up to some extent, 6 rats remained indifferent while the remaining 5 died due to brain tumors caused by stem cells. Basically, the treatment killed 20% of the recipients of ESC Therapy despite cautious and enormous attempts by the researchers based on their prior knowledge of deaths due to tumor formation. Therefore, overcoming the problem of tumor formation is going to be a mammoth task in terms of time, energy and resources. [46]

In the December 20/27, 2001, edition of Nature, Peter Aldhous, Nature's chief news and features editor stated that the 'the idea of 'therapeutic cloning' seems to be on the wane. Despite the possibility of deriving ES cells having identical genetic makeup as the patients**,** the procedure doesn't seem to be feasible in the regular clinic set-up seems since it is going to be exorbitantly expensive and burdensome to put it in a straight manner there won't be practically sufficient human eggs left.[47]

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[43] Carmel Shalev ,'Human Cloning and Human Rights: A Commentary'(2002)6(1) HHR Journal <https://www.jstor.org/stable/4065317accessed> 23 April 2020

[44] Nelson(n41)

[45] Shalev(n43)

[46] Wesley J. Smith , 'The False Promise of "Therapeutic" Cloning' *WASHINGTON EXAMINER* (11 March 2002)< https://www.washingtonexaminer.com/weekly-standard/the-false-promise-of-therapeutic-cloning> accessed 18 April 2020

[47] ibid

INTERNATIONAL AND NATIONAL LEGAL FRAMEWORK ON THERAPEUTIC CLONING

INTERNATIONAL CONVENTIONS/RESOLUTION OR DECLARATION:

The foundation for building a harmonious international consensus with respect to cloning was laid down through the UNESCO's Bioethics Programme of 1993. Out of the three declarations adopted by UNESCO, Article 11 of the Universal Declaration on Human Genome and Human Rights (1997) banned reproductive cloning however did not refer to therapeutic cloning in any manner.[48]

The Council of Europe has introduced rather ambiguous **'Convention on Human Rights and Biomedicine.'** (*hereinafter referred to as Oviedo Convention (1997)* which is not very clear in its approach towards therapeutic cloning.[49] Consequently, there came an **Additional Protocol of January 12, 1998 on the Prohibition of Cloning Human Beings** *(hereinafter referred to as Protocol on Cloning (1998)*. Through this Additional Protocol, prohibition is only with respect to the methods which lead to creation of clones of humans. However, the protocol does not directly regulate cloning of human tissues and cells, including embryonic stem cells thereby giving clarity on permissibility of therapeutic cloning.[50]

Even United Nations has not been able to bring out consensus of member states on the issue of cloning. In 2001, a committee was formed so as to discuss about an international convention against reproductive cloning. However, the debate continued for four long years wherein few member states proposed to ban even therapeutic cloning.[51]Eventually, UN passed a *nonbinding* Declaration on Human Cloning(2005) calling upon member states *"to adopt all measures necessary to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."*[52]

LEGAL APPROACH OF DIFFERENT COUNTRIES TOWARDS THERAPEUTIC CLONING:

United Kingdom , by the virtue of the Human Fertilisation and Embryology Act of 1990 provides that the human embryos can be created and used till 14th day of development for research

[48] The global governance of human cloning: the case of UNESCO, Adèle Langlois, Palgrave Commun 3, 17019 (2017) <https://www.nature.com/articles/palcomms201719>

[49]Richard Gardner and Tim Watson 'Patchwork of Laws'(*Scientificamerican* ,27 June 2005) <https://www.scientificamerican.com/article/a-patchwork-of-laws/> accessed 21 April 2020

[50]T Jasudowicz, 'Human Cloning From the Perspective of The Council of Europe Bioethical Standards'(2001) 5(1 Suppl 1) Med Wieku Rozwoz < https://pubmed.ncbi.nlm.nih.gov/11684779/> accessed 29 April 2020

[51] Gardner and Watson(n47)

[52] Rugnetta(n5)

purposes.[53] Further, in 2001 , the British Government passed Human Fertilization and Embryology (Research Purposes) Regulations, 2001 to amend the Human Fertilization and Embryology Act, 1990 thereby allowing therapeutic cloning.[54] There exists Human Fertilisation and Embryology Authority (HFEA) which is authorised to issue licenses for creation of human embryonic stem cells through nuclear transfer.[55] However, a separate license is required for each individual research project. Also, the 2001 amendment adds three research purposes granting researchers further possibilities to obtain a license which include increasing knowledge about embryonic development; increasing knowledge of severe diseases and transferring new insights into the therapeutic research of severe diseases.[56] It must be noted that while granting license, HFEA must be fully convinced that use of embryos is essential for purpose of the given research. Additionally, there must be a properly constituted Ethics Committee should approve every research project prior to the application made to the HFEA for a licence and it must also continue to report progress of the concerned research.[57].

United States' position on cloning is quite uncertain and interesting with respect cloning. United State House of Representative has attempted to vote on the issue of cloning on several occasions. As far as therapeutic cloning is concerned, no consensus was made as to whether ban or allow it. Consequently, state have come up with their own laws while some states wherein some have banned therapeutic cloning, while some states allow it for instance California.[58] It is interesting that a country as advanced as USA has not yet come up with any federal law with respect to cloning however there are federal laws and regulations to address the issues such as funding which are incidental to cloning.[59] In 2009 ,President Barack Obama through'2009 Guidelines on Human Stem Cell Research' lifted the 2001 ban imposed by former President George Bush on federal funding of research of Human Embryonic Stem Cells created after August 9, 2001.[60] However, research with the aim of creating human embryos for research purpose or for cloning of human embryos is still not eligible for federal funding.[61] Consequently , the researchers have to rely on private funding to continue research on cloning.

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[53] (n36)

[54]Ajai Kumar, 'Human Cloning: A socio-legal and ethical appraisal'(2010)52(1) JILI <https://www.jstor.org/stable/43953484> accessed 21 April 2020

[55] Rugnetta(n5)

[56] <http://www.drze.de/in-focus/research-cloning/legal-aspects> accessed 29 March 2020

[57] Dr Ruth Deech , 'Regulation of therapeutic cloning in the UK'(2002)5(1)RBMOnline< <https://www.rbmojournal.com/article/S1472-6483(10)61589-1> accessed 12 April 2020

[58] Kumar(n52)

[59] A Report of the Witherspoon Council on Ethics and the Integrity of Science, *Cloning Policy in the United* States(The New Atlantis- A journal of Technology and Society ,2015)

[60]Kirstin R.W. Matthews and Erin H. Yang, 'Politics and Policies Guiding Human Embryo Research in the United States' (Rice University's Baker Institute for Public Policy, January 2019).

[61] (n54)

INDIAN LEGISLATIVE FRAMEWORK WITH RESPECT TO THERAPEUTIC CLONING:

In India, there is no law specific dealing particularly on cloning however the issue has been addressed and regulated by ethical guidelines formulated in recent years by the concerned authorities. These were Ethical Guidelines for Biomedical Research on Human Subjects(2000), 'Ethical Policies on the Human Genome, Genetic Research and Services'(2001), and later on 'Ethical Guidelines for Biomedical Research on Human Participants'(2006)[62] However, at present, ICMR along with DBT has laid down **"National Guidelines for Stem Cell research" (2017)** wherein *restricted research involving use of embryonic and somatic(adult) stem cells for research purposes, creation of a human zygote via SCNT (Somatic Cell Nuclear Transfer) or any other method and therapeutic cloning has been permitted.* The guidelines also allow restricted research in in vivo experimentation in animals wherein human embryonic or adult stem cells at embryonic or foetal stages of development are introduced into animals. These guidelines were actually reviewed & analysed in line with the 2016 guidelines of International Society for Stem Cell Research (ISSCR), US.[63]

Most importantly, guideline provides for compulsory registration of the Institutional Committee for Stem Cell Research(ICSCR) and the Institutional Ethics Committee (IEC) with NAC-SCRT and CDSCO, respectively so that the clinical trials are conducted only in such institutes which are registered with IC-SCR and IEC, studies are conducted only at Good Manufacturing Practice (GMP)- and Good Laboratory Practice (GLP)-certified facilities and even the clinical research is undertaken by those practitioners who are not just registered with the Medical Council of India (MCI) but also possess a postgraduate qualification approved by MCI in the domain area of the specific trial.[64] In this way, the guidelines have fairly ensured sufficient checks and balances to ensure that stem cell research or therapeutic cloning is done fairly keeping in line with the intended objectives.

For basic research involving stem cells, the guidelines also requires in vitro studies to attain prior approval of IEC and IC-SCR and when such in vitro studies are intended to be done on preimplantation human embryos than the same must be done within a span of 14 days of

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[62] Kshitij. Singh, 'Human Therapeutic Cloning and Stem Cell Research: Ethical, Legal and Policy Implications.'(2014)<https://www.researchgate.net/publication/266377218_Human_Therapeutic_Cloning_and_Stem_Cell_Research_Ethical_Legal_and_Policy_Implications> accessed 24 April 2020

[63] Muntazir Ali Parvez Akhtar Sayed , 'M-20: Analysis of Indian National Guidelines for Stem Cell Research: A Path to Good Clinical Practice and Patient Care.'(2018) < https://www.diaglobal.org/en/flagship/dia-2018/program/posters/Poster-Presentations/Poster-Presentations> accessed 22 April 2020

[64]Sandeep Lahiry, Shouvik Choudhury, Rajasree Sinha and Suparna Chatterjee,'The National Guidelines for Stem Cell Research (2017): What academicians need to know?' (2019) 10 (4) ISCR <http://www.picronline.org/article.asp?issn=22293485;year=2019;volume=10;issue=4;spage=148;epage=154;aulast=Lahiry> accessed 24 April 2020

fertilization or formation of primitive streak whichever is earlier. Whenever derivation of human embryonic stem cells or induced pluripotent stem cells is required, then conditions for gamete, embryo, and somatic cell donation must be followed along with prior approval of IC-SCR and IEC.[65]The guidelines have also given certain provisions from the perspective of participant in the research i.e. the person who is the donor to facilitate the research since health, safety, and rights of the donor can't be simply neglected. Therefore, guidelines require mandatory video consent of the donor wherein the consent must be informed consent; screening for six major transmittable diseases namely HIV-1 and 2, hepatitis B virus etc. or any other risk factors for genetic disorders; IPRs of donated material will not vest with donor as such however may be shared (all this is to be mentioned in informed consent form).Also, if some financial gains arise on account of commercialisation than the donor need to be given part of same.[66]

Therefore, it can be denied that the National Guidelines on Stem Cell Research certainly is a significant step in right direction to encourage restricted stem cell research or even therapeutic cloning as they can pave way for major scientific developments in the near future. It has indeed clarified the ambiguity and loopholes of the preceding guidelines and has helped in preparing a basic skeleton of the research related to stem cell research and therapeutic cloning. However, despite the efforts, there are still instances which deviate the clinical research from the path of Good laboratory practices and has garnered a negative attention in the perception of the general public.

Recently, Union Minister of State for Health and Family Welfare informed that ICMR received plenty of complaints from various sources against the misuse of stem cell research.[67] When the Guidelines were framed one of the most important consideration was to curb rampant unethical practices being done under the garb of research including even therapeutic application. Such complaints, however, are suggestive that there is need for more stringent provision or enforcement action. As of now, as an immediate response complaint, ICMR has appealed to doctors across the country to share scientific proof of clinical efficacy of stem cells in any disease condition or disorder in their specialties so that malpractices can be curbed.[68]

Although, NGSCR makes it quite clear that stem cells can be used for therapeutic purposes in patients only in certain situations under haematolymphoid and immunological conditions, yet there are some clinics who are misusing the ignorance of the vulnerable patients and luring them to go

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[65] National Guidelines for Stem Cell Research, 2017

[66] Lahiry(n63)

[67] Neetu Chandra Sharma ,'ICMR asks stakeholders to share evidence on efficacy of stem cells'(*livemint,* 18 April 2019)< https://www.livemint.com/science/health/icmr-asks-stakeholders-to-share-evidence-on-efficacy-of-stem-cells-1555527812652.html> Accessed 22 April 2020.

[68] Ibid

for treatment with the help of stem cell research and therapeutic cloning even in case of diseases which are confined only for experimentation sake. Consequently, government has entrusted ICMR to frame laws for Hematopoetic (blood) Stem Cell Transplant [69]

Last but not the least, the Indian regime of therapeutic or research Cloning can be brought in line with the UK law and Indian law can bring in its counterpart of UK's Human Fertilisation and Embryology Authority (HFEA). No doubt there are Authorities which have been created under the NGSCR Guidelines 2017, but role of HEFA is more active and pivotal in permitting the research involving embryonic stem cells.

[69] Sharma(n 67)