

HUMAN CLONING- SOCIAL AND LEGAL ISSUES

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ABSTRACT

Cloning in biotechnology refers to processes used to create copies of DNA fragments (molecular cloning), cells (cell cloning), or organisms. Cloning is just one of several techniques potentially available to select, control, or alter the genome of offspring. When scientists refer to cloning, however, they are often referring to artificial cloning. This is most commonly achieved via a process known as somatic cell nuclear transfer (SCNT).ii There are three types of cloning: gene cloning, reproductive cloning, and therapeutic cloning.iii Human cloningiv is a controversial subject. It is a technology that has been artificially inhibited because there are religious concerns that make the science ethically non-viable. On the other hand, human cloning could also provide a medical answer to some of our most difficult diseases, birth defects, and genetic disorders that current have no treatments. Human cloning has the potential to help society in a number of key areas, from improving overall health care to the elimination of problematic diseases, there are some distinct advantages that the science of human cloning can provide. The development of such technology poses an important social challenge that is how to ensure that the technology is used to enhance, rather than limit, individual freedom and welfare. There are ethical and legal issuesv arising from the possibility that the cloning of humans could become a reality. Human reproductive cloning is illegalvi in most countries around the world, and will probably remain so until the technique has a much better success rate. Cloning laws and policies across the globe are not uniform and in some countries, it is sketchy. Most of the countries vehemently oppose human cloning while some allow therapeutic cloning and a few allow both types on animal cloning. Several ethical and legal issues have to be answered before allowing all forms of cloning. In India, the development of law in this regard is still on the drawing table. What is right as per both ethics and law depends upon political climate in the country, period and religion. This paper addresses the issues involved in attempting cloning. It outlines the debate on the issues relating to legal and ethical acceptance to cloning. This paper also highlights the lack of legislative framework and suggests the need to understand and address the issues arise out of corporate interests and commercial angle of cloning. This paper seeks to review the available legal provisions and regulatory authorities relating to human cloning.

Key words: Human; Cloning; Science; Technology; Ethics

Introduction:

The legal and ethical implications of cloning remained a low key issue until recently. The ethical aspects of cloning depend upon our perspective about its process. The development of law in this regard is still on the drawing table. What is right as per both ethics and law depends upon political climate in the country, period and religion. Both ethics and law are complimentary to each other. While there is no penalty involved for violations of ethics, law is always associated with punishment when it is violated. While ethics is not born of an institution, law certainly is. Interestingly, the countries around the world responded to the ethical and legal issues of cloning in varying ways. Most of the countries in the world, including India, have banned human cloning on ethical, religious and legal grounds but are positive on therapeutic cloning. We must advance the promise and cause of medical science and research, yet we must do so in ways that respect human dignity, help to build a better life culture that is conducive to build a better inclusive society.

Brief Description of Cloning:

Cloning, in simple terms, is just a blue print of another organism. The nucleus of a cell of an existing animal or person is inserted into a female egg from which the nucleus has been removed, and the resulting entity is stimulated so that it starts developing into an embryo. Embryonic stem cells are then derived from that clonal embryo. The cloning procedure is identical up to the stage at which a clonal embryo is either used for research purposes (therapeutic cloning), or implanted in the womb of a female animal or a woman (reproductive cloning). Therapeutic cloning is a multidisciplinary biotechnology that may be helpful in cell maintenance and improvement, restoration of cells and tissues and organ transplantation, involving biomedical branches of cell therapy, gene therapy, and tissue engineering.

In 1996, 'Dolly' the sheep was the first animal to be cloned in Scotland. Since then many other animals have been cloned like mice, goat, cow, pig, dog, rabbit, gaur and even a cat. Cloning of human being has not been attempted, at least officially, so far. However, cloning is not an easy technique. It seems that it is difficult to clone some animals. Frogs were cloned long time back while Dolly was the first sheep cloned. For reasons that are unknown or little understood, even the very few cloned animals that escape premature death develop abnormalities that are not associated with normal animals.

Need for Cloning:

Regenerative medicine has promising application in the fields of drug development, regenerative limbs, toxicity testing, treatment of untreatable diseases, understanding of diseases and tissue engineering. Alzheimer's, Parkinson's disease, cancer, certain forms of blindness, and diabetes could be cured. Other possibilities are reversal of ageing process, prevention of heart attacks. Skin for burn victims, brain cells for the brain damaged, spinal cord cells for quadriplegics and paraplegics can be made that does not get rejected by the immune system. Infertile couples could have children without having to go thru present day trauma. It could be used to produce perfectly-matched 'spare part' tissues for transplant. Scientists argue that the unreasonable restrictions that are in place on this branch of biomedicine is violation of fundamental right of a person. In a free society, people have the right to

pursue any scientific-and especially medical-investigation. Medical technology has already improved our lives immensely and will continue to support rather than destroy.

Objections:

Objections to cloning are based mainly on the principles of safety, humanity, morality and invariably on ethics. It is a known fact that current technology is quite unsafe. The failure rates in creating an embryo are very high. The survival rate of cloned animals is also abysmally low and the very few that survived had a very short span of life than normal animals. Also, the cloned animals suffered from heart problems, malformed arteries, diabetes, immune system deficiencies and physical deformities. And it is a tall order to expect human cloning also to be any different from the current scenario. It has to borne in mind that genetically identical does not mean it is totally identical because some important genes are also present in the mitochondria of the egg-cell. It might have its effect on the resultant embryo cells and it could spell problems in stem-cell treatment where compatibility is essential because of the risk of rejection. This part of research has not been perfected yet.

There are concerns that cloning may become another divisive class issue since the procedure could only be afforded by the affluent class. Since cloning involves asexual reproduction, the gene pool will be dramatically narrowed and it will severely dent the humanity's ability to overcome disease. Cloning represents an unprecedented control over the genetic make-up of another individual and puts restrictions on one's fundamental freedom. Cloning might be used to select or reject certain traits and the dangerous shadows of eugenics lurking on the society cannot summarily be ruled out. The cloned babies will fall into a separate class of single parented children since he is a product of asexual regeneration, confusing the identity and kinship relationships thus paving way to weaken the present notions of parental duties and children's responsibilities. Also, the cloned child may have to carry the psychological burden that he is a copycat of a genetic code and does not constitute a separate identity as others. A cloned child could see what he or she has the potential to become. Having insight into one's potential may cause enormous pressures to live up to expectations, more than those generally experienced by normal children.vii

The limited success of cloning will lead to commoditization of human cells and exploitation of women, especially underprivileged for their eggs that are needed to clone. Extraction of a very large number of eggs (due to low success rate) is a time consuming and invasive process which may lead to serious health problems of the women employed. Misuse of the technology is always a possibility, similar to selling of nuclear technology. A society has a right and an interest in how its members procreate and how families are created. Commoditization of human embryo is morally wrong and it disparages the very act of procreation challenging the very basics of ethics.viii

Legal position around the world:

Cloning laws and policies across the globe are not uniform and in some countries, it is sketchy. Most of the countries vehemently oppose human cloning while some allow therapeutic cloning and a few allow both types on animal cloning.

In South Africa, the Human Tissue Act prohibits both therapeutic and reproductive cloning of humans. However, therapeutic cloning is expected to be allowed, after an expected change of law, under strict conditions, requiring Ministerial permission. But reproductive cloning on humans will remain strictly prohibited.

In China, there are no laws against cloning. The Chinese government is showing extensive interest on cloning technologies and funding extensive research. It has called back home many Chinese scientists from abroad to take up research work which they would not be allowed in western countries or elsewhere. With unlimited funding, easy and unquestioned access to embryonic material they require, it is expected that China will occupy the podium in cloning technologies. The scientists claim that they have harvested 'stem cells' from human embryos that were cloned from eggs donated by patients at a fertility clinic. It is further claimed that they have created at least 30 cloned human embryos as a source of cells. It is said that they have been cloning embryos for two years, with five per cent surviving long enough to have their stem cells harvested. This breakthrough will prompt fears that it could go a step further and produce a cloned human baby.ix

In Singapore, Sweden and Israel, reproductive cloning is banned but scientists are allowed to generate new embryonic cell lines for therapeutic research. In UK, Human Reproductive Cloning Act and Human Fertilization and Embryology (Research Purposes) Regulations were enacted in 2001. The legislation explicitly prohibits human cloning. The research involving CNR embryos will be lawful only when it is under a licence from HFEA. The licences are to be granted for three distinct purposes viz. increasing knowledge about the development of embryos, increasing knowledge about serious disease and enabling any such knowledge to be applied in developing treatments for serious disease. The European Group on Ethics in Science and New Technologies (EGE) is of the opinion that since there are alternative sources for human stem cells, creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be premature.x Norway, Canada, Australia, France, Switzerland and Germany banned all forms of cloning. However, from 2002, Germany allows research on imported human embryonic stem cells.xi

There are no federal laws regulating human cloning in the United States. There is a prohibition on spending federal money on human embryo research of any kind, except in the case of embryonic stem cells that were created before 9th August, 2001. However, there is no ban on creation of embryos with private funds. Because of the opposing views from anti-abortion lobby which wants total ban all forms of cloning and the science lobby which backs a ban on reproductive cloning but not on therapeutic cloning, federal legislation is stalled. People are sceptic over FDA's authority over any attempts to ban reproductive human cloning.xii However, many states have passed laws on human cloning. State like Arizona, Arkansas, Michigan and few others prohibit both reproductive as well as

therapeutic cloning. Some states like California, Connecticut, and Illinois etc... prohibit reproductive cloning while permitting therapeutic cloning. Other states have laws that indirectly address human cloning, either by providing or prohibiting government funding for cloning research.xiii

Different rules in different countries enable the scientists, yearning for notoriety, to move abroad to carry out his research where it is legally allowed. To prevent this to happen, some countries like US want a global ban on all forms of cloning. In 2005, the UNO asked its member states to adopt such bans on all forms of human cloning and to adopt laws to “prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life”.xiv However many countries do not subscribe to the idea of total ban and hence no unanimous decision has been taken on this ban.xv

Legal position in India:

No other bio medical research or therapy involves scientific, moral, social and legal issues as therapeutic cloning. India permits cloning of animals, and encourages regulated research in this area and has even entered into cloning club in the year 2011. Since then many buffalo calves are cloned, both male and female in addition to goats. Indian scientists at National Dairy Research Institute at Karnal used a simpler inexpensive cloning process of “Advanced Hand Guided cloning Technique”. Cloning work on the Asiatic Cheetah is under progress now in a lab at Hyderabad. On research front, therapeutic cloning ,the government has positive views on the use of embryonic stem cells which has possibility of finding cure for various diseases. The LV Prasad Eye Institute in Hyderabad is working on stem cells to cure blindness. AIIMS, New Delhi carried out trials for repairing damaged heart muscles using stem cells.xvi

The Indian Council of Medical Research (ICMR), in February 1980, for the first time, released a ‘Policy Statement on Ethical Considerations involved in Research on Human Subjects’. But these were mere guidelines and since they lacked teeth, without any legislative support, they were hardly followed. There were instances of unethical researches carried out in India leading to dangerous propositions. After this, ICMR finalized a set of guidelines, “Ethical Guidelines for Biomedical Research on Human subjects” in 2000 which every Indian researcher is expected to adhere. These guide lines were further modified in 2006 and was put into force through Schedule Y. In 2007 another set of guidelines, together with the Department of Biotechnology regulating stem cell research and therapy were issued, specifically banning human cloning. The government established the National Apex Committee for Stem Cell Research and Therapy, NAC-SCRT. As per its guide lines, scientists conducting research on stem cells must be registered with the NAC-SCRT, and the creation of new stem cell lines must be approved by both the local and national review committees. The Guidelines divide research on human stem cells (including embryo stem cells) into three areas: permissible, restricted, and prohibited. The Guidelines also restrict clinical trials using cells that have undergone major manipulations such as genetic alteration.xvii They further restrict various forms of chimera research, such as the introduction of human ES cells into embryonic animals. The Guidelines prohibit germ-line engineering, human cloning

the growing of embryos in vitro for longer than fourteen days, transferring SCNT embryos into a uterus, and the breeding of animals that have received human ES cells.xviii The three basic ethical principles viz. Respect for person, beneficence and justice were elaborated by inducting the following twelve general principles.

Principle of essentiality, Principles of voluntariness, informed consent and community agreement, Principle of non-exploitation, Principle of privacy and confidentiality, Principle of precaution and risk minimisation, Principle of professional competence, Principle of accountability and transparency, Principle of the maximisation of the public interest and of distributive justice, Principle of institutional arrangements, Principle of public domain, Principle of totality of responsibility and Principle of compliance.xix For a research to be ethical, it is mandatory that the above principles are to be strictly followed. In a third world country like India, these concepts occupy a special place since most of the research participants are mostly from uneducated economically backward section of the society. Some clinics are resorting to extort money from gullible patients in the name of stem cell therapy. However, there is no conclusive proof of safety or therapeutic efficacy of stem cells in any condition yet and it is not part of a standard care. To arrest the exploitation of patients, ICMR has issued a new set of guidelines in 2014 which prohibits the use of name “therapy” and will be considered as research in any use of stem cells in patients. According to ICMR, the new curb on the name therapy will put an end to the unethical practice of offering stem cell treatment as a therapy for curing untreatable diseases. It will be considered a malpractice if stem cells are used in patients outside an approved clinical trialxx. However, as said before, these guidelines have to be ably supported by suitable laws for proper implementation, as in other parts of the world by the Ministry of Health.

Conclusion:

The regulation of human cloning continues to be a significant issue. The notion of "human dignity" is commonly used to justify cloning laws. The basis for this justification is that reproductive human cloning necessarily infringes notions of human dignity.It is very difficult to answer whether cloning is beneficial to the human community or not. The genesis of the 21st century is a period of unequal technological, military and economic prowess combined with unparalleled moral and ethical vacuum. Scientists certainly have an important voice in policy debates on these matters, but history is replete with instances and dangers of human experimentation. There is no guarantee that the technology will not be misused that may really prove very dangerous. Several ethical and legal issues have to be answered before allowing all forms of cloning. To prevent the possible misuse, reproductive cloning should be banned internationally till the world community including the jurists, scientists, sociologists, ethicist and theologians finds out answers to legality and morality issues of human cloning and mandatorily their views shall be taken in set forth in laws, regulations and other directives. India shall promote ethical scientific and medical research, and not merely the progress of research.

ⁱThe term clone, invented by J. B. S. Haldane, is derived from the Ancient Greek word "twig", referring to the process whereby a new plant can be created from a twig.

ⁱⁱThe first useful human embryonic stem cells were created by Shoukhrat Mitalipov and colleagues using SCNT in 2013. These produced stem cells for an 8-month-year-old with Leigh syndrome, a rare genetic disorder. Subsequently, this process was repeated using adult somatic cells by Young Gie Chung, Robert Lanza and colleagues from the Research Institute for Stem Cell Research in Los Angeles, and the CHA Stem Cell Institute in South Korea.

ⁱⁱⁱGene cloning is essentially recombinant DNA technology, where a piece of foreign DNA is inserted into a vector, which can be copied by a host cell. Therapeutic cloning involves the production of patient-matched stem cells for disease treatment. Reproductive cloning is the process by which a whole organism is cloned. First, a cell is taken from the organism that is being cloned. The DNA from this donor cell is then transferred to an egg cell whose DNA has been removed. The egg cell is "activated" and begins dividing as if it was fertilized. An embryo results, and this embryo is then transferred to the uterus of a surrogate female. After gestation is complete, the surrogate will give birth to the clone, which is a genetic copy of the animal from which the original cell was taken.

^{iv}The first human was cloned by American biologist Samuel Wood, and Australian biologist Andrew French, in 2008. Woods cloned himself using a donated human egg, but did not succeed in creating stem cells. Biologists Dieter Egli and Scott Noggle became the first to produce human embryonic stem cells using SCNT, while working at the New York Stem Cell Foundation Laboratory, in 2011. However, their process only worked when the eggs' nucleus remained in the cell. This meant that these embryos had three, rather than two, sets of chromosomes, and would not be compatible with their genetic donor.

^vCloning is a form of asexual reproduction. A child produced by cloning would be the genetic duplicate of an existing person.

^{vi}Reproductive cloning is inherently unsafe. At least 95% of mammalian cloning experiments have resulted in failures in the form of miscarriages, stillbirths, and life-threatening anomalies; some experts believe no clones are fully healthy. The technique could not be developed in humans without putting the physical safety of the clones and the women who bear them at grave risk.

^{vii}December 16, 2012, [krishnaa](http://www.krishnaa.com), Legalservicesindia.com - A Brief Study on Human Cloning and Ethics

^{viii}JIAFM, 2005 ; 27 (3). ISSN 0971 – 0973 Reproductive cloning – An act of human right violation, Dr. R.K. Bansal

^{ix}www.dailymail.co.uk/health/article-127836

^xJIAFM, 2005 ; 27 (3). ISSN 0971 – 0973 Reproductive cloning – An act of human right violation, Dr. R.K. Bansal.

^{xi}Source: <http://www.pub.ac.za/factfile/cloning.html>

^{xii}NPR.org Aug 2nd, 2016, www.ipsell.com/2013/05/last visited on 2nd Aug, 2016.

^{xiii}www.thenewatlantis.com/docLib/20150825_TNA46Appendix.pdf

^{xiv}<http://www.un.org/law/cloning/#2004>

^{xv}<http://www.pub.ac.za/factfile/cloning.html>

^{xvi}BaglaPallava 24, Jun,2009Should India ban human cloningNew Delhi: NDTV.

^{xvii}It would seem to include many iPS cells and ANT-derived stem cells.

^{xviii}www.thenewatlantis.com/.../appendix-e-overview-of-international-human-embryonicstem-laws.

^{xix}Indian J Pharm Sci. 2011 Mar-Apr; 73(2): 125–130. Ethics in Clinical Research: The Indian Perspective, J. Sanmukhani and C. B. Tripathi

^{xx}February 24, 2014, The Hindu on line.