CHALLENGES FOR LAW IN REGULATING STEM CELL RESEARCH, THERAPEUTIC AND REPRODUCTIVE CLONING: A GLOBAL PERSPECTIVE

*L. Pushpakumar**

I. INTRODUCTION

The humankind stands now at an historic juncture.[1] Never before in the history has humanity been so unprepared for the new technological and economic opportunities, challenges and risks that lie on the horizon. Our way of life is likely to be more fundamentally transformed in the next several decades than in the previous one thousand years.[2] By the year 2025, Jeremy Rifkin observed in 1998, "we and our children may be living in a world utterly different from anything human beings have ever experienced in the past. In little more than a generation, our definition of life and the meaning of existence is likely to be radically altered. Long-held assumptions about nature, including our own human nature, are likely to be rethought. Many age-old practices regarding sexuality, reproduction, birth, and parenthood could be partially abandoned. Ideas about equality and democracy are also likely to be redefined."[3]

At present, we are facing the scenario contemplated by Jeremy Rifkin. With the advent of new tools in biotechnology, nanotechnology and advancements in biomedical research, many new developments such as cloning, stem cell research and gene therapy make possible many new cures for the humanity's innumerable diseases such as cancer, AIDS, Alzheimer's disease, Parkinson's disease etc. Biomedical research assures miracles to

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* Lecturer, Law Centre–I, Faculty of Law, University of Delhi, Delhi.

1 Statement of Prof. Alexander Morgan Capron, Commissioner of National Bioethics Advisory Commission, USA, and Henry W. Bruce, University Professor of Law and Medicine, Co-Director, Pacific Center for Health Policy and Ethics, University of Southern California Law Center, testifying before the Subcommittee on Crime Committee on the Judiciary, United States House of Representatives, June 19, 2001, while speaking on his own behalf about the legal and ethical issues involved in Human Cloning.

2 Rifkin Jeremy, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD (1998) at 1.

3 *Ibid.*

medical industry, which could turn out to be boon as well as bane for the global humanity. The human kind is now under a compulsion to take decisive decisions as to the regulation and permissibility of technology in a variety of fields, particularly in the field of biomedical research.

Stem cell research, therapeutic and reproductive cloning have been seriously pursued by many countries. Countries like Belgium, China, India, Israel, Japan, Singapore, South Korea, South Africa, UK and USA are enormously investing in stem cell research. Yet most of the countries do not have effective regulatory framework to deal with stem cells research.

Law, as an instrument of regulating human behaviour, has a pivotal role to play in this historic moment. The DNA technology and genomic age posit a new set of challenges to the lawmakers and implementing agencies. Regulation of the hitherto unknown areas of activities unleashed by modern biomedical research would be a phenomenal task for the policy and lawmakers. Many social, political, economic, legal, ethical and philosophical considerations call for thorough analysis of permissibility of modern biomedical research. The potential risks involved in the process ought to be regulated by a well- framed regulation at the national and international level. What are the precautions to be taken while allowing such inherently dangerous and at the same time beneficial research? How to harness the benefits of technology for the promotion of global health? What are the ethical issues involved in such venture? What are the changing dimensions of IPR issues, genetic privacy, human rights and dignity of human beings? These are some of the major questions the humanity has to answer and the law has to respond while embarking upon not a frequently ventured arena. The paper attempts to track the recent trends in biomedical research with special reference to human stem cell research, therapeutic and reproductive cloning and their health care policy implications at the global level. The paper also proposes to account for the ethical considerations leveled against those research activities and the challenges for law in regulating biomedical research. The paper maintains that while human therapeutic cloning can be encouraged, human reproductive cloning shall not be allowed at any cost. The paper also calls for international convention on bioethics and human stem cell research so that global consensus can be achieved.

II. Modern Trends In Biomedical Research

A. Stem Cell Research

Stem cells are the master cells that are capable of developing into any tissue or organ in the body. Researchers believe that stem cells could be useful as regenerative tool to treat a wide variety of diseases such as

cardiovascular disease, diabetes, osteoporosis,[4] cancer, Alzheimer's disease,[5] Parkinson's disease,[6] birth defects, spinal cord injuries, severe burn injuries etc.

Stem cells are available in small numbers in living human body in most organs including the liver, blood, and brain. Stem cells have two crucial capabilities: (1) they divide repeatedly into stem cells of their own type; and (2) with appropriate stimuli they can develop or differentiate either into one particular tissue, or into a small number of tissues or, as in the case of pluripotent embryonic stem cells, into potentially all types of tissues. For years, pluripotent embryonic stem cells have been viewed as the holy grail for many scientists, particularly developmental biologists.[7] In 1998 the scientists discovered the process of purifying Embryonic stem cells (ESCs) and maintaining them in culture in the laboratory. ESCs are derived from embryos at the blastocyst[8] stage, which is approximately five to seven days after fertilization. At this state, within the blastocyst, there is a small fluid collection (cyst) in the embryo and at one pole of the cyst a specialized clump of cells known as the inner cell mass. It is from this inner cell mass that ESCs can be obtained. Researchers have now developed the ability to separate early, undifferentiated stem cells from the blastocyst stage that eventually develops into an embryo.

Until quite recently, it was thought that stem cells found in adult tissues and organs could differentiate only into the particular type of cells that make up the organ where the stem cell resides. However, over the past few years it has been repeatedly demonstrated that stem cells originating from one organ or tissue can develop into cell types of another tissue. This has been shown in both animals and humans. Nonetheless, there are reports that cast doubt on the notion that adult stem cells are as versatile as ESCs.[9] If adult stem cells are proved to be as flexible as ESCs, the scientists may utilize adult stem cells instead of ESCs and avoid much of the ethical problems associated with ESCs.[10]

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[4] Osteoporosis occurs in bone due to decrease in mass and becoming porous which is susceptible to frequent fractures.

[5] Alzheimer's disease causes due to irreversible damage to the brain and leads to memory loss and ultimately to death.

[6] Parkinson's is a neurological disease resulting in death of brain cells associated with emotions and motor control.

[7] See Abdullah S. Daar and Lorraine Sheremeta, *The Science of Stem Cells: Some Implications for Law and Policy*, 11 (1) HEALTH LAW REVIEW at 1.

[8] Blastocyst is the early stage of mammalian embryo.

[9] *Supra* n. 7 at 4.

[10] *Id.* at 6.

B. Cloning

Cloning refers to "making an identical (or near identical) genetic copy".[11] The term cloning is used in three different contexts. It sometimes refers to the process of copying a fragment of DNA so that there are enough identical fragments for a scientist to study. For instance, criminologists use a method of DNA cloning called polymerase chain reaction (PCR) when they need to make many copies of a tiny bit of DNA found in blood, hair, skin, or semen at the scene of a crime. That is a widely accepted form of cloning used in labs around the world every day. Then there is reproductive cloning, a technology for creating an entirely new animal (the clone) from the genetic material of an existing animal (the donor). Dolly, the sheep, was created with reproductive cloning technology. The third category is therapeutic cloning – the cloning of human embryos to harvest stem cells for medical uses – is accomplished the same way as reproductive cloning. The difference is, instead of implanting the embryo in a woman, scientists destroy it so that researchers can extract its stem cells, which are master cells capable of morphing into different kinds of cells, such as those in the brain, muscles, or other organs, and which might be used for medical treatment.[12]

The subject of cloning became a matter of public debate and concern after the announcement of the cloning of the sheep Dolly in 1997. The public was concerned that human beings would be cloned for inappropriate purposes. In this context, we need to distinguish between "therapeutic cloning" and "reproductive cloning".[13]

Reproductive cloning, by nuclear transfer from a differentiated somatic cell[14], although conceptualized and developed in other species over decades of research, became a reality in mammals only in 1997. Somatic cell nuclear transplant (SCNT) involves the fusion of somatic cell with an enucleated egg, or the transfer of a nucleus of a somatic cell into an enucleated egg. The somatic cell and egg may be from different individuals or from the same individual.

Where SCNT is initiated without the intention of implanting the blastocyst in a uterus, it is termed as "therapeutic cloning". Although SCNT is the starting point for both reproductive cloning and therapeutic cloning, the important distinction lies with the fact that with "therapeutic cloning"

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[11] *Ibid.*

[12] Gina Smith, THE GENOMICS AGE: HOW DNA TECHNOLOGY IS TRANSFORMING THE WAY WE LIVE AND WHO WE ARE, (2005) at 158-60.

[13] *Supra* n. 7 at 6.

[14] Somatic cell is any body cell other than sex cells, i.e. the sperm or egg cells.

there is no intention of implanting the resultant blastocyst into a uterus of an animal or a human to create a living being.

Therapeutic cloning is simply used to create a blastocyst that provides a source from which ESCs can be extracted and cell lines created for research. One possible application of ESCs is to use them to make cells, tissues and/or organs that can be transplanted back into the same person who donated the somatic cell nucleus. This technology is important because it may provide a solution to the significant problem of shortage of organs for transplantation and of the rejection of transplanted organs and tissues by the recipient's immune system.

C. Human Cloning

The birth of Dolly by SCNT method hit the hornet's nest as the general public, policy makers, ethicists and even the scientists got worried about the possibility of application of this method to create human beings. If such an event happens, that would signify 'the first step on a slippery slope that would inevitably result in cloned children'.[15] Even the cloned animal Dolly was euthanized within a period of six years as it developed several complications including premature arthritis and cancer which was attributed to the cloning process.

Scientists feel that animals born through reproductive cloning using SCNT develop genetic abnormalities. This raises the likelihood that stem cells, and by implication, cells, tissues and organs derived from them, may be in some way defective and that the defects may not be apparent until quite late in the life of the transplanted cells, tissues or organs. However, the science is at a very early stage and this possibility is one further argument for continuing research in this area.[16]

While there are some who find it acceptable to clone human beings, the vast majority of commentators consider human reproductive cloning to be unethical. There is a near consensus among the countries that human cloning must be banned and in fact many countries brought out legislations to that effect. Strangely enough there are also supporting voices for human cloning. Dame Mary Warnock, the Chair of the Warnock Commission in the UK based on whose report the Human Fertilisation and Embryology Act, 1990 was passed in UK, has "called for the blanket ban on human cloning

[15] Opinion of Krauthammer in the President's Council on Bioethics on April 25, 2005. See, Stephen S. Hall, *Human Cloning: President's Bioethics Council Delivers*, 297 SCIENCE, 19 July 2002 at 322-24.

[16] *Supra* n. 7 at 8.

to be lifted and has stated that she supports cloning of babies for infertile couples. She believes that in future there should be no major ethical obstacles to human reproductive cloning for medical reasons if it can be proven safe."[17]

If the slippery slope argument proves to be true, that could be the worst thing to happen in the human history and would write obituary to humanity. Recently the UN has adopted a declaration which bans human cloning. But unfortunately it fails to distinguish between "therapeutic cloning" and "reproductive cloning" and imposes a blanket ban on all forms of cloning. On this count alone, the declaration failed to achieve consensus among the community of states.

As human cloning is unethical and dangerous there should be no second opinion on banning it completely. At the same time, therapeutic cloning which is beneficial to mankind due to its potential utility in health sector must be allowed with adequate regulatory system.

A group of Korean researchers Hwang Woo-suk and his team claimed[18] that they have cloned the world's first human embryo and extracted stem cells from it. They reported that the first human embryonic stem cell line produced with somatic cell nuclear transfer (cloning). There are several doubts regarding this supposed breakthrough.[19]

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[17] Templeton, *Cloning – One Step Closer*, THE SUNDAY HERALD, July 28, 2002.

[18] W. S. Hwang, et. al., 308 SCIENCE, May 2005 at 1777.

[19] The Seoul National University has commissioned tests on cell samples taken from scientist Hwang Woo-suk's laboratory amidst reports that earlier results have created stem cells individually tailored to patients. The investigation panel has asked three outside labs to conduct the DNA tests to determine whether Mr. Hwang was ever able to develop a colony of stem cells from a cloned embryo as he claimed in a May article in the journal *Science*. It was claimed that the panel found at least 9 out of 11 stem cell lines documented in the article were fabricated and the other 2 cell lines were under investigation. On the other hand, South Korea's Yonhap News Agency reported that some test results already received showed that some stem cells created after the paper was published did match patient's DNA. Scientists felt that the development of stem cells that match a patient's DNA is a huge leap toward treatments for incurable afflictions such as Alzheimer's disease and diabetes. The University authorities planned to commission more investigations to obtain an accurate and prudent analysis. In the meantime, Mr. Hwang apologized for the fabrication and stepped down as Professor at the University. He insisted, however, that his team has developed the technology to create patient-matched stem cells. See *University Orders More DNA Tests on Hwang's Stem Cell Research*, THE HINDU, December 28, 2005.

III. The Bioethics Debate

The benefits and perils of what some are calling "the ultimate technology frontier" are both exciting to behold and chilling to contemplate.[20] While the power and possibilities of biotechnology are comprehended by people, the ethical issues about the potential threats and possibilities of cloning in human beings are beginning to pour from all concerned quarters. The bioethics[21] debate has started to emerge as a powerful force against the stem cell research and cloning in the West, particularly in the US it has become very controversial. Ethical questions pertaining to DNA databases, gender selection, genetic testing, genetic counseling, preimplantation genetic diagnosis, are being seriously debated. Legitimacy of embryonic stem cell research, cloning, especially human cloning became very contentious unresolved issues. Utilization of human genome project and permissibility of genetic testing are nagging the policy makers and ethicists for lack of clear directions.

There are few areas of modern biomedical research that have aroused as much controversy as stem cells.[22] These new experimental medical strategies did not only raise positive expectations with respect to the treatment of serious diseases and conditions but also created a great deal of controversy and put pressure on policymaking. Whereas tissue engineering and

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[20] *Supra* n. 2 at 2.

[21] The term 'bioethics' has at least two different meanings, one broader than the other. The term was used for the first time by Van Rensselaer Potter in 1970 who advocated a comprehensive and global view of bioethics; on the other hand, André E. Hellegers used the term 'bioethics' for the first time in an institutional way for an academic field of learning and a movement regarding public policy and the human life sciences. Bioethics in this view is a new way of approaching and resolving moral conflicts generated by a new concept of medicine. This more restricted view has become dominant in much of the theory and practice of bioethics. In the present context "bioethics" refers to the systematic, pluralistic and interdisciplinary study and resolution of the ethical issues raised by medicine and the life and social sciences as applied to human beings and their relationship with the biosphere, including issues relating to the availability and accessibility of scientific and technological developments and their applications. See *Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics*, First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics, UNESCO Headquarters, 4-6 April 2005.

[22] Abdullah S. Daar and Lorraine Sheremeta, *The Science of Stem Cells: Some Implications for Law and Policy*, 11 (1) Health Law Review at 6.

[23] Xenotransplantation is the process of transplantation of organs from one species to another, especially animals to humans.

bioartificial organs have remained relatively uncontested. xenotransplantation[23] and, in particular, therapeutic cloning and embryonic stem cell research have given rise to heated debates in Europe and in the United States. What some interpreted as a "medical revolution," others saw as an attempt to create "superhumans," as a revival of Nazi eugenics[24] in new clothes, or as a potential public health disaster.[25]

Embryonic stem cell research, cloning, and xenotransplantation are medical strategies that stir emotions, create camps of fervent supporters and dedicated opponents, and stimulate discussions about the meaning and direction of modern medicine. Currently, in most Western countries bioethicists, philosophers, lawyers, scientists, and other kinds of experts ponder about the acceptability, the limits, and the promises of these new research strategies, which focus on the recovery, manipulation, and utilization of cells from humans and animals for medical purposes. They discuss different methods, such as transplanting tissues or organs from genetically modified pigs to humans, removing embryonic stem cells from aborted fetuses in order to create and transplant neural precursor cells, and taking cells from a person for using them to clone a blastocyst and thus obtaining stem cells.[26]

The birth of Dolly was the starting point of debate. Within days of the announcement about cloning of sheep in 1997, President Clinton of the USA responded immediately to the emotions of public and imposed a ban on federal funding related to attempts to clone human beings. In addition, the President directed the National Bioethics Advisory Commission (NBAC) to report within 90 days on the ethical and legal issues that surround the potential cloning of human beings. The NBAC engaged itself in an intensive and open examination of the topic, hearing from experts in law, science, medicine, ethics, religion as well as from members of the general public and submitted its report, *Cloning Human Beings*, to the President. The Commission focused mainly on the reproductive human cloning and not on

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[24] The term eugenics used to refer the process of improvement of human species by selective breeding with the help of those individuals with desirable genetic characteristics. It was practiced during Nazi Germany to encourage the pseudoscientific 'master race' by eliminating unfit and feeble minded persons. This was highly disfavoured as it led to the sterilization of thousands of people and murder of people in the name of 'social undesirables'.

[25] Herbert Gottweis, *Stem Cell Policies in the United States and in Germany: Between Bioethics and Regulation*, 30 (4) POLICY STUDIES JOURNAL, 2002 at 444-69.

[26] *Supra* n. 22.

research (or therapeutic) cloning and found out that the potential ability to clone human beings through SCNT raises a host of complex scientific, religious, legal, and ethical issues, especially the medical risks to any child conceived in this manner. The Commission concluded that no one – whether federally or privately supported – should be permitted to create babies through cloning at that time and recommended a moratorium be imposed on such research. It was believed that a moratorium would give society a safeguard not only against extreme risks to any child created in this fashion but also against the possible harms that might accompany crossing the line to controlled, asexual "reproduction". A moratorium would also provide a period of time both for further knowledge to be accumulated about mammalian cloning and for serious and sustained reflection about the sort of world that human cloning could create and then, three to five years hence. Congress or the President of the US would decide whether the results of the scientific research and of the debate on the risks and potential benefits of human cloning had provided sufficiently strong reasons to lift the prohibition and permit human cloning under any circumstances. As the technology was still in infancy at that time, the Commission did not attempt to write a final word on the issue but instead provided a starting point for what they hoped would be the profound and sustained reflection their nation needed on the subject on human cloning.[27]

When the researchers succeeded in creating for the first time the human pluripotent stem cell lines from embryos remaining after infertility treatments and aborted fetuses in 1998,[28] the NBAC again engaged itself in analyzing its implications and came out with the report *Ethical Issues in Human Stem Cell Research* and suggested for appropriate changes in statutes and regulations to allow federal funding of research involving the derivation and use of human stem cells from aborted fetuses and from embryos that would

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[27] See the Statement of Prof. Alexander Morgan Capron, Commissioner of National Bioethics Advisory Commission, USA, and Henry W. Bruce Professor of Law, University Professor of Law and Medicine, Co-Director, Pacific Center for Health Policy and Ethics, University of Southern California Law Center, testifying before the Subcommittee on Crime Committee on the Judiciary, United States House of Representatives, June 19, 2001.

[28] Researchers at the University of Wisconsin and Johns Hopkins University announced in November 1998 that they had for the first time succeeded in creating human pluripotent stem cell lines from embryos remaining after infertility treatments and aborted fetuses. See J. A. Thomson, *et. al.*, *Embryonic Stem Cell Lines Derived from Human Blastocusts*, 282 SCIENCE, 1998 at 1145; M.J. Shamblott, *et. al.*, *Derivation of Pluripotent Stem Cells from Cultured Primkordial Germ Cells*, 95 PROC. NAT'L. ACAD. SCI., 1998 at 13726.

otherwise be discarded, subject to appropriate ethical standards and procedures that include public oversight and review. The commission also recommended that research involving the derivation or use of stem cells from human embryos made, using SCNT, should not be eligible for federal funding at that time. However, NBAC noted that there was significant reason to believe that use of stem cells from such embryos may have therapeutic potential, due to the utility of matched tissue for autologous cell replacement therapy, and stated that scientific progress and medical utility in this area of research should be monitored closely. NBAC did not address whether or not this research should occur in the private sector.[29]

NBAC had several courses of action under consideration on the question of cloning. One would have been no moratorium on any activities. The second would have been a moratorium on both reproductive as well as research cloning. The third, which was the one that the commission actually chose, was a temporary moratorium on reproductive cloning, but no moratorium on research cloning. In doing so, NBAC recognized that while important moral considerations were at stake, with respect to research and reproductive cloning, the nature of those moral considerations were different in kind. With respect to research cloning, the issues are those associated, in general, with the embryo research debate. With respect to reproductive cloning, however, the issues pertained to the safety of the fetus and mother and the potential impact of reproductive cloning on the resultant children and their institutions of parenting and child bearing. It was because of the difference between these types of considerations that a moratorium was considered appropriate in one case (reproductive cloning) but not the other (research cloning). At the time it considered stem cell research, the commission once again considered the question of research cloning. There it concluded that the case had not yet been made for a need for federal funding for that activity. It did not, however, propose a moratorium on privately funded activity in this area.[30]

Prof. Alexander Morgan Capron in his personal capacity opined that had a stronger justification been shown for using SCNT to create embryos for stem cell research he doubted NBAC would have opposed federal funding. The fact was the need for cloning human embryos was simply not established, given the rudimentary state of the science on such matters as

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[29] *Supra* n. 24.

[30] *Ibid.*

[31] *Ibid.*

mammalian cloning in general or controlling the differentiation and development of cells and organs from pluripotent stems cells. In addition, NBAC recognized the availability of human embryos remaining after fertility treatments to meet the needs of researchers.[31]

In July 2002, the President's Council on Bioethics delivered its recommendations to the President regarding the federal policy on human cloning. The deeply divided panel by a 10-7 margin recommended that the government should ban cloning for reproductive purposes and observe a 4 year moratorium cloning for biomedical research. However a minority of Council members expressed support in principle for research cloning.

A human embryo has a special status as a potential human being, but it does not have the same status as a living child or adult. It should not be seen as disrespecting the embryos, but rather as enabling them to serve a greater good by being used for research – which is an act of greater respect for these embryos.

There is a view that the creation of embryos through therapeutic cloning does offer an opportunity to derive stem cells which are immunologically compatible with the person being treated, thereby avoiding the problem of rejection. In February 2003, Singapore ES Cell International has paved the way for stem cell treatment that offers hope for diabetic patients, as its scientists have the means to develop insulin producing to respond effectively to such scientific advances and discoveries.

Different religions possess different stand points with regard to stem cell research. For example, in Singapore, the National Council of Churches of Singapore, the Catholic Medical Guild of Singapore, the Sikh Advisory Committee, and the Singapore Hospice Association have strong contentions that a human life begins from the moment of conception. Others such as the Majlis Ugama Islam Singapura held the view that a human life does not begin until some time after conception. The Buddhist Federation in Singapore supports research on the view that it is ethically irresponsible to deny the progress of scientific research that would benefit mankind.[32]

From 1998 to the present, advisory groups and government panels in at least 23 countries and 5 international political bodies have studied and commented on human embryonic stem cell research. During this time, 18 different committees in 12 countries have concluded that permitting the

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[32] Catherine Tay Swee Kian and Tien Sim Leng, *The Singapore Approach to Human Stem Cell Research, Therapeutic and Reproductive Cloning*, 19(3) BIOETHICS. 2005.

conduct of human SCNT research is an acceptable public policy. The groups espousing this view include the Nuffield Council on Bioethics in the United Kingdom, the National Consultative Committee on Ethics in France, Israel's Bioethics Advisory Committee, Singapore's Bioethics Advisory Committee, the Dutch Health Council, and the British House of Lords Select Committee on Stem Cell Research.[33]

While there is universal agreement not to permit human cloning, the opinion is divided regarding use of embryonic stem cells for therapeutic cloning. Equally controversial is the issue of sex determination of embryo. It is obviously justified if it is required for preventing birth of a genetically compromised child. The psychosocial, ethical and legal consequences of surrogate motherhood following in vitro fertilization (IVF) technology can no longer be kept under the carpet since there is already an increasing demand for the same. The emerging fields of behavioural genetics and the potentials for manipulating brain functions have already raised alarms about their possible misuse in absence of well-defined ethical guidelines. Attributing the client's criminal action to some genetic predisposition lawyers have begun to plead in the courts of law absence of responsibility or culpability of their client for the criminal offence committed.

In the UK the Royal Society preferred moratorium instead of an outright ban on reproductive cloning. According to Gardner, "The reason why the Royal Society advocated a global moratorium on human reproductive cloning rather than outright prohibition is that a full and open discussion of the issues that it raises might lead to recognition of circumstances in which its use was considered appropriate".[34]

While there exists a near global consensus about banning of human reproductive cloning amongst the vast majority of experts, commentators and States, as evidenced in the practices of individual States in their respective countries and their declared positions while voting for the United Nations Declaration on Human Cloning in the General Assembly in August 2005, still there are some who find it acceptable to clone human beings.[35]

Ethical considerations have strong force in the society and for that matter they cannot be overlooked. Ethics also happen to be the basis of law

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[33] Le Roy Walters, *Research Cloning, Ethics, and Public Policy*, 299 (5613) SCIENCE, 14 March 2003 at 1661.

[34] Gardner, Richard L., *Therapeutic Cloning and Reproductive Cloning – A Scientific Perspective*. (Oxford: Oxford University, 2002) at 6-7, quoted in *id.* at 207.

[35] See, *supra* n. 22.

making most of the times. Yet, at the same time the society cannot afford to stifle the development of science and technology in the name of assumed factors. An effective interdisciplinary approach must be adopted to seriously explore and examine the sociological, political, economic, ethical, philosophical and legal implications of cloning and stem cell research. The implications of intellectual property rights over patenting of genetic materials should also be resolved.

IV. Redefining Health Law And Policy

In the light of the recent developments in biomedical research, a new look at the health care law and policy is imperative. The purpose of science is (or ought to be) improvement of human life and alleviation of human sufferings. The human curiosity to unravel the secrets of nature with the help of emerging technology brings alongside it new kinds of problems and creates new provinces of jurisprudence.

Norman Daniels[36] has logically extended the theory of justice propounded by John Rawls[37] and has related it to justice in health care. Daniels has made the compelling argument that access to basic health care is a requirement of justice. A goal of public health and medicine is to keep people as close as possible to the ideal of normal functioning, under reasonable resource constraints. The question is how can this goal be accomplished on a global scale, and what sorts of public policies are needed to make progress toward that goal?[38] Only recently have bioethicists begun to explore inequalities in health and health care in the international sphere.[39] There is a strong nexus between global health care and emerging revolution in science and technology. According to Harvard University President Larry Summers, the most important issues facing mankind today are the health of people in the developing world, particularly people in Africa and the emerging revolution in the life sciences which for the first time, is providing us with a fundamental understanding of human nature.[40]

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36 N. Daniels, Just Health Care (Cambridge: Cambridge University Press, 1985).

37 J. Rawls, A Theory of Justice (Cambridge: The Belknap Press, 1971).

38 Ruth Macklin, *Bioethics and Public Policy in the Next Millennium: Presidential Address*, 15 (5/6) Bioethics, 2001at 373-81.

39 *Id.* at 374.

40 Summers L., *Remarks of President Lawrence H. Summers, School of Public Health Leadership Council Inaugural Meeting,* Cambridge, Massachusetts. October 21, 2003, quoted in Abdallah S. Daar, Puja Sahni and Peter A. Singer. *Genomics, Biotechnology and Global Health: The Work of the University of Toronto Joint Centre For Bioethics*, X (2) Acta Bioethica 2004 at 213-25.

The new and rapidly advancing field of genomics and related biotechnologies has the ability to either improve or worsen global health inequities. In general, developing countries are left behind in the development of new technologies and advances in genomic medicine.[41] This widening gap between modern science and technology and the accessibility of the same to the needy in the developing world to improve their health has to be reduced. Innovation in science and technology has significantly contributed to medical advances and has consequently had a large impact on public health. The benefits of this progress, however, have yet to be equally shared globally. Millions of people in developing countries continue to face health challenges that no longer burden the industrialized world. With pandemics such as HIV/AIDS plaguing countries in sub-Saharan Africa, life expectancies in this region is 40 years and falling – nearly half of those in developed countries. This immense disparity in global health equity is perhaps the greatest ethical challenge of our time.[42] Global health inequity is one of the most important ethical issues facing the world today.[43] It is evident in the large differences between life expectancy figures for industrialized and developing countries. Life expectancy in Canada is 80 years and rising; in sub-Saharan Africa, it is 40 years and falling. Inequities exist in the number of deaths due to preventable diseases – a figure much higher in the developing world than in the industrialized west. There is also a 10/90 gap: only 10% of public and private health research expenditure is devoted to the health issues affecting 90% of the global population.[44] Most genomics researches also focus on health issues affecting the wealthiest countries in the world. Scientists feel that genomics–related technologies have the potential to improve the health equity gap.[45] The World Health Organization, in its 2002 report on *Genomics and World Health*, also urges Member states to build genomics and bioinformatics capacity for research towards their own health priorities in order to address global health inequities.[46]

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41 See A. Daar, et. al., *ibid.*

42 Peter A Singer, et. al., *The Critical Role of Genomics in Global Health*, 2 GLOBAL FORUM UPDATE ON RESEARCH FOR HEALTH at 113-14.

43 *Supra* n. 29.

44 Global Forum for Health Research, *The 10/90 Report on Health Research 2003-2004*, quoted in *id.* at 214.

45 *Supra* n. 29 at 116.

46 GENOMICS AND WORLD HEALTH, Report of the Advisory Committee on Health Research, World Health Organization, Geneva 2002.

However, a view that extends beyond genomics and biotechnology is required in order to truly harness the potential of science and technology to improve global health. Other fields such as nanotechnology and regenerative medicine can also have a large impact on increasing global access to health care. Nanotechnology, for example, currently offers a cheap alternative to current diagnostic tests through the lab-on-a-chip, a microfluid device that can test for numerous diseases at a time. Regenerative medicine also has tremendous therapeutic potential: autologous bone marrow stem cells are currently being tested in patients for treatment of heart disease, a promising development in light of the dramatic increase in levels of cardiovascular disease in developing countries. The benefits of genomics and biotechnology are already being felt in developing countries.[47]

The moot question is how cost effective it would be for the people living in developing countries to access the modern treatments. How many people could afford to avail super specialty treatments given their pitiable economic status? What would be the role of national governments in such a scenario?

Some encouraging signs are visible at the global level. One of the efforts being the Millennium Development Goals (MDG) initiated under the auspices of the UN which aims at reducing global poverty, hunger, disease, illiteracy, environmental degradation and discrimination against women by the year 2015.[48] Another ambitious project the University of Toronto Joint Centre on Bioethics (JCB)'s Canadian Program on Genomics and Global Health (CPGGH) involving 25 research and capacity enhancement projects aimed to reduce the genomics divide and improve global health equity.[49] Their *Top 10 Biotechnologies for Improving Health in Developing Countries* project identifies the ten most promising biotechnologies which could be used for improving health in developing countries.[50] Another major initiative is

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47 *Supra* n. 29 at 116.

48 See IMPLEMENTING THE MILLENNIUM DECLARATION: THE MILLENNIUM DEVELOPMENT GOALS AND THE UNITED NATION'S ROLE (United Nations Department of Public Information, October 2002).

49 See Canadian Program on Genomics and Global Health (CPGGH) 2004 at www.geneticsethics.net visited on December 23, 2005.

50 The top 10 biotechnologies include, Molecular Diagnostics, Recombinant Vaccines, Vaccine & Drug Delivery, Bioremediation, Sequencing Pathogen Genomes, Female-Controlled Protection Against Sexually Transmitted Infections, Bioinformatics, Enriched GM Crops, Recombinant Drugs, Combinatorial Chemistry. Full report available online University of Toronto Joint Centre for Bioethics. TOP 10 BIOTECHNOLOGIES FOR IMPROVING HEALTH IN DEVELOPING COUNTRIES (2002). http://www.utoronto.ca/jcb/home/news_genomics.htm visited on December 25, 2005.

from Bill and Melinda Gates Foundation (BMGF) under the title *Grand Challenges in Global Health* involving $200 million medical research grant. The University of Toronto Joint Centre for Bioethics (JCB) is providing methodological support for this programme.[51] A global genomics network is also mooted to harness and equitably distribute the benefits of genomics among the countries. Canada has proposed to set apart not less than 5% of their research and development to a knowledge-based approach to develop assistance for less fortunate countries. Similar kind of 5% commitment by European Union and the US (if they come forward) would result in an additional $9.3 billion and $14.1 billion devoted to developing country challenges, respectively.[52]

V. Differing National Legal Regimes

Countries adopt different approaches in allowing stem cell research and therapeutic cloning. However, human reproductive cloning is by and large disallowed by all countries. The World Stem Cell Map published by[53] the Columbia University Medical Center reveals the global status of stem cell research in different countries. Countries like United Kingdom, Belgium, Sweden, Israel, India, Singapore, China, Japan, South Korea, South Africa, follow permissive approach to stem cell research. Embryonic stem cell derivation techniques including somatic cell nuclear transfer (SCNT), also called research or therapeutic cloning is permitted. Australia, Brazil, Canada, France, Spain, The Netherlands, Taiwan adopt flexible approach in which derivations from fertility clinic donations only are permitted, excluding SCNT, and often under certain restrictions. Research is permitted only on remaining embryos no longer needed for reproduction. Countries with a restrictive policy include (among the most restrictive) Austria, Ireland, Norway, Poland, (among the less restrictive) Germany, Italy, and the United States. Restrictive policies range from outright prohibition of human embryo research to allowing research on imported embryonic stem cell lines only to permitting research on a limited number of previously established stem cell lines. A law in the Czech Republic regulating embryonic stem cell research is pending. Turkey is among several countries in which no specific regulations and guidelines have so far been defined by legal or governmental institutions for human embryonic stem cell research. The positions of some of the countries are discussed below.

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[51] See, H. Varmus, et. al. *Public Health Enhanced: Grand Challenges in Global Health (Policy Forum)*, 302 (5644) Science, 17 October 2003, at 398 -99.

[52] *Supra* n. 30.

[53] Columbia University Medical Center, Stem Cell Reception Brochure, June 21, 2005.

A. USA

Stem cell research and human cloning have become extremely contentious issues in the US. President Clinton has instituted a ban on federal funding related to attempts to clone human beings in 1997.[54] On the basis of religious beliefs, the House of Representatives banned all forms of human cloning from 2001. Now federal funding is allowed for embryonic stem cell research only on cells already in existence. The National Bioethics Advisory Commission monitors all federally funded ES cell research. President Bush has banned embryonic stem cell research in any federal institution or any federally funded research program except for some already existing cell lines.

The Human Cloning Prohibition Act, 2003 prohibits human cloning.[55] It is also unlawful to import an embryo produced by human cloning or any product derived from such embryo. Nonetheless the Act does not restrict areas of scientific research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos. tissues, organs, plants, or animals other than humans.

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[54] Harold T. Shapiro, *Ethical and Policy Issues of Human Cloning (Policy Forum)*. 277 (5323) SCIENCE, 11 July 1997 at 195-96.

[55] Sec. 302. Prohibition on human cloning:

(a) In General - It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly-
  (1) to perform or attempt to perform human cloning;
  (2) to participate in an attempt to perform human cloning; or
  (3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.

(b) Importation - It shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning or any product derived from such embryo.

(c) Penalties -
  (1) Criminal Penalty - Any person or entity that violates this section shall be fined under this title or imprisoned not more than 10 years, or both.
  (2) Civil Penalty - Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than $1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than $1,000,000.

(d) Scientific Research - Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

As the Federal support is not forthcoming, the US National Science Academy has offered its own guidelines for stem cell research in May 2005. However, the State of California has given green signal to stem cell research. Approved by California voters on November 2, 2004 Proposition 71 provides constitutional right to a State to pursue stem cell research, including through Somatic Cell Nuclear Transfer or therapeutic cloning, and prohibits funding of human reproductive cloning research.

Only 12 of the 50 states currently ban human SCNT research, either specifically or through prohibiting all research on early human embryos. In the remaining 38 states, SCNT research involving human eggs and early embryos is not legally proscribed. California studied the question of human embryonic stem cell research with the aid of an interdisciplinary advisory committee. After a multiyear deliberative process, this large, diverse state enacted a law that supported human SCNT research. A federal ban would immediately preempt this new law. Bills that expressly permit human SCNT research have been introduced in the legislatures of 12 additional states. The states are Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Maryland, Kentucky, Tennessee, Indiana, Missouri, and Washington.[56]

On December 20, 2005, the President of the USA has signed the Stem Cell Therapeutic and Research Act of 2005, which creates a new Federal program to collect and store cord blood, and expands the current bone marrow registry program to also include cord blood. The legislation requires that the Secretary of Health and Human Services contract with qualified cord blood stem cell banks to facilitate the collection and maintenance of human umbilical cord blood. Collected cord blood would be made available for transplantation or research and distributed via a program within the Health Resources and Services Administration. Additionally, the Act also establishes a searchable database of available cord blood as well as a scientific database tracing patient.

It is felt that the UK could benefit from the regulatory differences between the US and UK. It is predicted that as a consequence of the prevailing situations in the US, Britain will see an influx of scientists from the U.S. In 2001, for example, Professor Roger Pedersen, a pioneer in this area, took up a position at Cambridge University's Department of Surgery. Professor Pedersen's laboratory was only one of six to have isolated stem cells from human embryos. There are also reports that a number of U.S.

[56] R. Willing, USA TODAY, 25 Feb 2003 at 3A. See Le Roy Walters, *Research Cloning, Ethics, and Public Policy*, 299 (5613) SCIENCE, 14 March 2003 at 1661.

biotech companies are considering moving their research programs to the UK.[57]

B. United Kingdom

UK strongly supports stem cell research. The Human Fertilization and Embryology Act, 1990 permits experimentation on human embryos up to the 14 days post fertilization stage, and prohibits nuclear substitution of any cell whilst it forms part of an embryo.[58] The Act requires a license from the Human Fertilization and Embryology Authority for any creation, use, or storage of a human embryo outside the body.[59] Any one who wants to pursue SCNT requires a license from the Authority. All treatment clinics offering in vitro fertilization (IVF) or donor insemination, or storing eggs, sperm or embryos, conform to high medical and professional standards and are inspected regularly. The Authority is empowered to license and monitor all human embryo research and overseeing research in the field as well as considering the ethical implications of a number of key issues.

US regulation of stem cell research has had a direct effect on the UK science effort. In the opinion of Richard Gardner, Professor of Zoology at Oxford University, the UK government's recent decisions to allow therapeutic cloning will make reproductive cloning more likely, and will certainly do so in the sense of generating the know-how necessary for improving the efficiency of obtaining healthy cloned conceptuses. Moreover, since such technical advances are normally published in the open scientific literature, this information will be just as freely available in countries that do not have the relevant legislative controls as in those that do.[60]

With regard to the biomedical field, the European Commission has established the European Group on Ethics in Science and New Technologies, the support for research in bio-ethics and the introduction of ethical principles and evaluation for Community research support. With regard to therapeutic cloning – where the UK has the lead – and the UK government's adaptation

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[57] Helen Lawton Smith, *Regulating Science and Technology: The Case of the UK Biotechnology Industry,* 27 (1) LAW & POLICY, January 2005, 189-212 at 207. However, Professors like Kay Davis, Head of the Oxford Centre for Gene Function, said that she would not do some work in China because of the less strict regulatory system, see Davis, Kay, *Creating Knowledge – New Initiatives in Oxford,* 2002, in seminar on Genetics Knowledge in Oxford – Networks and Opportunities? at Business School, Oxford, 30 October.

[58] Section 3 (3)(d) Human Fertilization and Embryology Act, 1990.

[59] Section 3(1), *id.*

[60] *Supra* n. 34.

in January 2001 of the 1990 Human Fertilization and Embryology Act to allow therapeutic cloning research to be carried out on fourteen-day-old embryos left over from IVF treatment, has led to the European Parliament's establishing of the Temporary Committee on Human Genetics. This will provide guidance for the European Parliament on what regulation may be necessary.[61]

C. Singapore

In Singapore, there is no law to regulate research on human embryos. The Guidelines for Private Healthcare Institutions Providing Assisted Reproduction Services[62] provide for the use of human embryos below 14 days that were created through IVF techniques, but which are not used in assisted reproduction treatments, provided stringent regulatory stipulations are met.

The Regulation of Biomedical Research Bill was introduced in November 2003. The Bill seeks to regulate the conduct of biomedical research and ban certain types of research. However, Singapore decided to adopt a step-by-step approach to the regulation of human stem cell research and cloning. She started with the more pressing issue of human reproductive cloning by enacting the Human Cloning and other Prohibited Practices Act, 2004. Separate laws will subsequently be developed for human embryonic stem cell research and human tissue research. Section 5 of the Human Cloning and Other Prohibited Practices Act specifically prohibits the implantation of a human embryo clone in the body of a human or an animal. Further, it is not a defense to this criminal offence that the human embryo clone could not have survived. However, therapeutic cloning of human embryos for research is allowed under special circumstances. Section 7 bans the implantation of any human embryo in a woman created by any process other than fertilization of a human egg by a human sperm, for a period of more than 14 days. It is an offence for any person to develop any human embryo outside a woman body for more than 14 days. Section 9 forbids any person to remove any human embryo from a woman body to collect a viable human embryo. It is also an offence to place any prohibited embryo in the body of a woman. This Act also bans the importation and exportation of human embryo clones. It also prohibits the commercial trading in human eggs, human sperms and human embryos. The criminal penalties for contravening the provisions of Human Cloning and Other Prohibited

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[61] Helen, *supra* n. 57.

[62] Regulation 4, Private Hospitals and Medical Clinics Regulations.

Practices Act are a maximum fine of $100,000 or a maximum imprisonment of ten years or both.[63]

D. India

India is the 10th largest industrialized country in the world, with the 3rd largest pool of scientific and technical professionals. The country has a well-established pharmaceutical industry and has made forays into the biotechnology sector, with support from the government as well as industry innovation. It also continues to be the world leader in the Information Technology sector, which has spawned a burgeoning bioinformatics industry. At the same time majority of its population live in poverty and have poor access to modern medicine. Scientists view that the country's biotechnology industry has made huge strides over the last ten years and that genomics has the potential to alleviate India's health problems.[64]

The Indian biotechnology industry is ranked third in the world in terms of stem cell research, primarily because both the government and private industry have invested heavily in research institutes studying stem cells.[65] As India ventures into genomics and bioinformatics, it will be important to prioritize the country's health needs and strategic entry points. An estimated 4 million people are living with AIDS in India, over 2 million people are infected with malaria per year and over 420,000 Indians die annually from tuberculosis. On the other hand, chronic diseases like cancer, diabetes and heart disease are also prevalent in India and pose a rising health concern. Both these broad categories of disease present R&D opportunities for India. Moreover, India's biotechnology and pharmaceutical industries are also in a good position to prioritize and develop indigenous technologies. For example, the announcement by the US Department of Health in 2002 of 64 stem- cell lines that will be funded by the US federal government creates opportunities for stem cell research in India – Reliance Life Sciences has 7 of these cell lines.[66]

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[63] For a detailed analysis of Singapore scenario, see Catherine, *supra* n. 32.

[64] GENOMICS POLICY EXECUTIVE COURSE REPORT, An Indo - Canadian initiative by Indian Council of Medical Research and University of Toronto Joint Centre for Bioethics for Harnessing Genomics to Improve Health in India, January 20 - 23. 2003, Kumarakom , Kerala, India.

[65] Tara Acharya, et. al., *Harnessing Genomics to Improve Health in India – An Executive Course to Support Genomics Policy,* 2:1 HEALTH RESEARCH POLICY AND SYSTEMS 2004, May 2004

[66] *Ibid.*

In January 2002, the Department of Biotechnology (DBT) also articulated priority research areas for government funding in biotechnology. These areas include vaccines based on genomic research for cholera, malaria, AIDS, rabies and tuberculosis as well as biofertilizers, biopesticides, transgenic crops, and gene therapy for cancer treatment. A biotechnology vision document released in late 2001 outlines additional plans over the next 10 years and includes developing edible vaccines for specific diseases targets, testing and approving a series of GM crops, developing additional vaccines and diagnostic tools for major communicable diseases, as well identifying and protecting biodiversity "hot spots." There is considerable concern among NGOs and other stakeholders in India that the DBT's goals are too broad and difficult to realize. Draft National Biotechnology Development Strategy (2005) also emphasises harnessing the benefits of modern biomedical research particularly stem cell research.[67] Moreover, it is doubtful that these activities will help to meet the health needs of the economically weaker sections of society.

The regulation of biomedical research in the country is still in a nascent stage. The Indian Council of Medical Research issued a "Policy Statement on Ethical Considerations involved in Research on Human Subjects" in 1980. In September 1994, the Government of India notified the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act. The ICMR has over the years issued policy statements and guidelines primarily concerned with ethical aspects of research on human subjects. It has a standing Central Ethics Committee on Human Research (CECHR). Similarly the Medical Council of India has a committee on Medical Ethics which has issued a code for medical practice.

In 1998, the National Academy of Sciences, India, organized an International Bioethics Symposium on *Human Genome Research: Emerging Ethical, Legal, Social and Economic Issues*. As a follow-up of the recommendations of this symposium, the Department of Biotechnology, Government of India established a National Bioethics Committee. Following detailed deliberations, it has issued a document on "Ethical Policies on the Human Genome, Genetic Research and Services". This is an elaboration of the guidelines included in the ICMR document. A nominee of this committee is represented on the UNESCO Inter-governmental Bioethics Committee

[67] DRAFT NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY prepared by the Department of Biotechnology, Ministry of Science & Technology, Government of India, 2005

(IGBC). The Committee thus provided inputs to the UNESCO deliberations on human genetic data.[68]

Despite all these developments and prospects for stem cell research in India, the people at large, even those who are eventually connected with these activities, are almost ignorant of what is going on around them and there is no healthy debate or policy initiative in the country. India needs a clearly articulated genomics and biotechnology policy that will focus on biomedical research to meet domestic needs.

The Indian Council for Medical Research has come out with Guidelines for Stem Cells Research / Regulation in India in 2004. Still it is in a draft stage only. The Government of India has not yet taken any final action on this. As of now there is no policy or legal framework which regulates stem cell research in India.

VI. The Evolving International Order: Unesco's Efforts On Bioethics

Practice of medicine has since time immemorial been guided by ethical principles. The best known of these were enshrined in the Hippocratic Oath. However, long before that equally enlightening principles were pronounced by *Charak* and *Susruta*, the pioneers of the Ayurvedic system of medicine. These primarily referred to doctor-patient relationship.[69] Nevertheless, modern bioethics is founded on values enshrined in the Universal Declaration of Human Rights (1948). Other texts of different legal force establishing rules for the protection of persons in the wide field of biomedicine include the Nuremberg Code adopted by the United Nations General Assembly in 1947, the Declaration of Helsinki (1964) of the World Medical Association (WMA) , Declarations of Tokyo (1975), Venice (1983) and Hong Kong (1989) – and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1992) prepared and recently revised by the Council for International Organizations of Medical Sciences (CIOMS).

At the regional level, the American Convention on Human Rights (1978) and the African Charter on Human and Peoples' Rights (1981) also contain provisions relevant to bioethics. The only existing conventional instrument is the Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, which was drawn

[68] See, P.N. Tandon, *Bioethics: An Emerging Discipline*, Indian J Med Res, January 2005 at 121.

[69] *Ibid.*

up within the framework of the Council of Europe, adopted in 1996 and in force since 1997. An additional Protocol is already in force and another is open for signature. The main purpose of the Convention is to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedom with regard to the applications of biology and medicine"[70]. The Convention also declares that "the interests and welfare of the human being shall prevail over the sole interest of society or science".[71] On the other hand, the Charter of Fundamental Rights of the fifteen countries of the European Union, adopted at the Nice Summit in 2000, includes other points of bioethical interest that are related not only to biology and medicine: the right to life (nobody can be condemned to capital punishment); the right to physical and mental integrity, to freedom and personal security; the refusal of torture and inhuman punishments or treatments, of slavery and forced labour, but also include "positive rights" connected with fundamental needs, such as health and education, and that demand action and implementation of public policies.

UNESCO has been a pioneering international body in the field of bioethics and has established two advisory bodies – the International Bioethics Committee (IBC) and the Inter-governmental Bioethics Committee (IGBC). IBC is the only global forum for in depth biological reflection by exposing the issues at stake which was established in 1993. IGBC was created in 1998 to examine the advice and recommendations of IBC.[72]

UNESCO has contributed to the formulation of basic principles in bioethics through three major instruments – the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997, the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003 and the Universal Declaration on Bioethics and Human Rights adopted by the General Conference of UNESCO on 19 October 2005.

The Universal Declaration on the Human Genome and Human Rights, 1997 was the first step in the direction incorporating the fundamental principles in bioethics. The Universal Declaration on the Human Genome and Human Rights is limited in its scope, as it applies only to the human

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[70] Article 1 of the Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1996

[71] Article 2, *id.*

[72] For more details see http://portal.unesco.org visited on 23 December 2005.

genome. At the same time, it specifically mentions examples contrary to human dignity, such as the reproductive cloning of human beings[73] and germ-line interventions.[74] It also underlines the role of the International Bioethics Committee in identifying practices contrary to human dignity and sets forth distinct principles on ethical values that should be considered in the international instrument, such as prior, free and informed consent, no financial gain, confidentiality, non discrimination and solidarity.

The International Declaration on Human Genetic Data, 2003 was adopted to ensure the respect of human dignity. The Declaration aims[75] to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data,[76] human proteomic data[77] and of the biological samples[78] from which they are derived, referred to hereinafter as "biological samples", in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research; to set out the principles which should guide States in the formulation of their legislation and their policies on these issues; and to form the basis for guidelines of good practices in these areas for the institutions and individuals concerned. Any collection, processing, use and storage of human genetic data, human proteomic data and biological samples shall be consistent with the international law of human rights. The provisions of this Declaration apply to the collection, processing, use and storage of human genetic data, human proteomic data and biological samples, except in the investigation, detection and prosecution of criminal offences and in parentage testing that are subject to domestic law that is consistent with the international law of human rights.

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[73] Article 11 of the Universal Declaration on the Human Genome and Human Rights,1997.

[74] Article 12, *id.*

[75] Article 1, International Declaration on Human Genetic Data, 2003.

[76] Human genetic data means the information about heritable characteristics of individuals obtained by analysis of nucleic acids or by other scientific analysis. See, Article 2(i), *id.*

[77] Human proteomic data denotes the information pertaining to an individual's proteins including their expression, modification and interaction. See Article 2(ii), *id.*

[78] Biological samples means any sample of biological material (for example blood, skin and bone cells or blood plasma) in which nucleic acids are prese. See Article 2(iv), *id.*

The Universal Declaration on Bioethics and Human Rights, 2005 recognizes that ethical issues raised by the rapid advances in science and technological applications should be examined with due respect to the dignity of the human person and universal respect for and observance of human rights and fundamental freedoms. The Declaration emphasizes that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technical developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments. The Declaration aims to provide a universal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments in the field of bioethics.[79] Article 3 of the Declaration protects human dignity, human rights and fundamental freedoms and puts the interests and welfare of the individual at the centre stage. Scientific research should be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequately provided along with modalities for withdrawal of consent by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in the Declaration and international human rights law.[80] Privacy and confidentiality of personal information of persons are protected under the Declaration. The privacy of persons concerned and the confidentiality of their personal information should be respected to a greatest extent possible. Such information should not be used for purposes other than those for which it was consented to or collected. [81] Though the Universal Declaration of Bioethics and Human Rights 2005 is a significant declaration as far as bioethics is concerned, it is unfortunate that it does not even mention about stem cell research and cloning.

VII. UN BAN ON HUMAN CLONING

The Health Assembly first considered the subject of human cloning in 1997, affirming that "the use of cloning for the replication of human beings is ethically unacceptable and contrary to human integrity and morality".[82]

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[79] Article 2(a), Universal Declaration on Bioethics and Human Rights, 2005.

[80] Article 6.1, *id.*

[81] Article 9, *id.*

[82] REPRODUCTIVE CLONING OF HUMAN BEINGS: STATUS OF THE DEBATE IN THE UNITED NATIONS GENERAL ASSEMBLY, Report by the Secretariat, World Health Organization, Executive Board, EB115/INF.DOC./2 115th Session 16 December 2004.

The following year, the Fifty-first World Health Assembly reaffirmed that "cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity". To date, some 35 countries have adopted laws forbidding human cloning. Some prohibit only cloning for reproductive purposes and allow the creation of cloned human embryos for research, whereas others prohibit the creation of cloned embryos for any purpose. International documents such as the Universal Declaration on the Human Genome and Human Rights, adopted by the UNESCO General Conference in 1997 and endorsed by the United Nations General Assembly the following year, and the World Medical Association's Resolution on Cloning, endorsed in 1997, have confronted the issue but lack binding legal force.[83]

The UN General Assembly recently adopted the United Nations Declaration on Human Cloning, 2005 calling on the 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. The Declaration also calls on the Member States to protect adequately human life in the application of life sciences; to prohibit the application of genetic engineering techniques that may be contrary to human dignity; to prevent the exploitation of women in the application of life sciences; and to adopt and implement national legislation in that connection.

The Assembly commenced the work on an international convention on human cloning four years ago, but failed to forge a consensus on the vexed issue of global importance. The Declaration was adopted by a vote of 84 in favour to 34 against, with 37 abstentions. This is because of the reason that most of the states are in favour of therapeutic cloning and the term "human life" contained in the text was ambiguous and confusing and could be interpreted as a call for a total ban on all forms of human cloning. However, there was a global consensus for reproductive human cloning.

VIII. Conclusions

The development of science signifies the maturity of human race in unlocking the secrets of nature and harnessing them for the benefit of humanity. The preceding discussion reveals that technology promises a significant leap forward for the humanity in its known history – to make, unmake, fine-tune, design differently or cure humans – in many new ways. Are we ready for this process? What kind of science and technology we could afford to permit? What amount of restraint is needed at this hour? The human

[83] *Ibid.*

race as a whole has to decide now. Technology is good as long as it is within our control. For that matter regulation should not stifle the development of science and technology which would prove to be benevolent to the human race however small segment of people it could be. At the same time the mandate of science and technology must be to benefit the global health of human beings and not to complicate life.

Swift precautionary regulatory approach would solve the uncertainty over stem cell research. As of now there is no global vision and regulatory framework in the field of biotechnology and nanotechnology assisted biomedical research, particularly relating to cloning and stem cell research, barring a few UNESCO Declarations on Bioethics and Human Rights. The regulation of biomedical research is largely in the national domain. This would make the global governance of medical biotechnology uneven and complex as the harmful effects of biotechnology will not confine themselves within the limits of national boundaries alone rather they will affect the entire global environment and human health. Different strategies and legal measures adopted by different nations will pave the way for uneven standards and prevent uniformity of legal and policy measures in dealing with modern biomedical research. Global consensus has to be achieved to have a holistic approach to the biomedical research and a comprehensive legal framework has to be evolved covering all issues. The legal framework should endeavor to promote global health and prevent disparities and inequity in health care initiatives. It should also aim at minimizing its lethal implications and maximizing its benefits. The issue of liability for any potential harm to the persons utilizing advanced biomedical research and those used in such process has to be settled. In the final analysis, it is submitted that there should be an international convention on bioethics and human stem cell research so that a consensus can be reached internationally with minimum standards and safeguards to be placed at national levels.