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# **GOLDEN GATE UNIVERSITY SCHOOL OF LAW**

MORAL AND LEGAL ISSUES CONCERNING CONTEMPORARY HUMAN CLONING TECHNOLOGY

- QUEST FOR REGULATORY CONSENSUS IN THE INTERNATIONAL COMMUNITY TO SAFEGUARD

**RIGHTS AND LIBERTIES ESSENTIAL TO THE FUTURE OF HUMANITY** 

.....

CHING-POU SHIH, JD, LL.M, SJD CANDIDATE

.....

#### SUBMITTED TO THE GOLDEN GATE UNIVERSITY SCHOOL OF LAW, DEPARTMENT OF INTERNATIONAL LEGAL STUDIES, IN FULFILMENT OF THE REQUIREMENT FOR THE CONFERMENT OF THE DEGREE OF SCIENTIAE JURIDICAE DOCTOR (SJD).

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# **Introduction**

#### I. Background and Resources

In 1997, veterinary researchers Drs. Ian Wilmut and Keith Campbell of the Roslin Institute in Scotland shocked the world by announcing the birth of the first cloned mammal, Dolly the sheep. With the introduction of Dolly, the international community has realized that the practice of human cloning will become real and possible. The idea of human cloning is moving from the realm of science fiction into the realm of real possibility. Dr. Lee Silver, a molecular biologist at Princeton University, is optimistic and stated in 1998 that "human cloning will occur," and that "it might take five years, ten years at the outermost."<sup>1</sup>

Since Dolly, several other species of mammals, such as goats, mules, pigs, cows, cats, mice and rodents have also been successfully cloned around the world. With regard to the possibility of the realization of any kind of cloning for any species of animals or plants and even for our human beings in the near future, the international community has inevitably raised many

<sup>&</sup>lt;sup>1</sup> See Wilmut I., Schnieke A.E., McWhir J., Kind A.J., Campbell K.H.S., Viable Offspring Derived from Fetal and Adult Mammalian Cells, 385 NATURE 810-813 (1997)

debates concerning the benefit and impact of deeply-rooted human rights in our contemporary society if the development of current cloning technology is completely or partially acknowledged or opposed.

Among others, these debates have tried to address many key issues such as the negative effect of religious belief, mishaps or lapses in quality control of cloning technology, the welfare of human beings, the individuality and dignity of lives, and the recommendation and enactment of conceivable legislation effectively guiding the framework and governing the development of technology of human cloning.

Of course, human cloning technology engages not only religious, cultural, social, and moral challenges, but also ethical and legal issues, as well as human and fundamental rights concerns; in particular, liberty of procreation, right to health, and freedom of thought and scientific inquiry.<sup>2</sup> Since each country or specific district may have its own view and perspective on the occurrence of contemporary human cloning, different nations or regions are formulating policies, laws, and pertinent regulations in distinctive ways.

The international community, led by the United Nations and other major international organizations, is inclined to overwhelmingly take its unavoidable responsibilities to evaluate different opinions among many nations or districts as to the ethical, legal and scientific value of

<sup>&</sup>lt;sup>2</sup> See Mahnoush H. Arsanjani, Negotiating the UN Declaration on Human Cloning, 100 AM. J. INTL. L. 164 (2006)

today's human cloning technology and try hard to ultimately enter into a profound compromise for them. No matter the decision that would be made against or in favor of the development of human cloning technology, the dilemma should be reviewed and addressed based on common and adequate norms and standards under contemporary well-recognized regime of humane-based jurisprudence.

## **II.** Motive and Purpose

In confronting this situation, the research topic for this dissertation would focus its efforts on resolving at least two questions as follows: First, what are the major moral and legal problems in current human cloning technology and what are the intelligent choices of public policy? Second, how could respective nations, regions, and the international community corporately clarify those problems in the realm of contemporary human dignity imperative and human rights jurisprudence?

There are several types of cloning that have been practiced by scientists, such as molecular cloning, cellular cloning, and embryo cloning.<sup>3</sup> Embryonic cloning can further be

<sup>&</sup>lt;sup>3</sup> Molecular cloning is the foundation of recombinant DNA technology. DNA fragments containing gens are copied and amplified in a host cell, usually a bacterium. Cellular cloning is a technique that cells are grown in a culture in a laboratory to make copies of them and are derives from soma, or body. The genetic make-up of the resulting cloned cells, called a cell line, are identical to the original. Both procedures are very useful in the testing and lead to

divided into three forms: blastomere separation, blastocyst division or twinning, and nuclear transfer.<sup>4</sup> The cloning technique, used by the Roslin Institute to Clone Dolly, is a form of nuclear transfer. Since nearly all mammal eggs are almost the same size, scientists conclude that the cloning procedure ought to be applicable to most mammals, including humans. The technique of nuclear transfer in embryonic cloning is a magnet for most attention of the world.

Therefore, "Cloning," "Human Clone" or "Human Cloning" may be defined in a variety of aspects. "Cloning" defined by the Inter-Academy Panel on International Issues, statement on Human Cloning (Trieste, Italy, 22 September 2003) as follows:

[C]loning of an organism commonly involves a technique called somatic cell nuclear transfer, where the nucleus of an egg cell (containing its genetic material) is removed and replaced with the nucleus of a somatic cell taken from the body of an adult. If the reconstructed egg cell is then stimulated successfully to divide, it may develop to the preimplantation blastocyst stage. In reproductive cloning, the cloned blastocyst is then implanted in the uterus of a female and allowed to continue its development until birth. However, in cloning for research or therapeutic purposes, instead of being implanted in the uterus the cloned

the production of many important medicines, such as insulin to treat diabetes. Since molecular and cellular cloning of this sort do not involve germ cells (eggs or sperm), they are not for the purpose to produce a baby.

<sup>&</sup>lt;sup>4</sup> Blastomere separation involves the splitting of the embryo soon after fertilization (2-8 cells). Each cell is called a blastomere and is able to produce a new individual organism. Blastocyst division or twinning involves the splitting into two identical halves of an embryo that has been sexually formed. The two parts can be transferred to the uterus and both halves are capable of giving rise to identical twins. Nuclear transfer involves a transfer of a nuclear from each blastomere of a four-to-eight-cell or later-stage embryo into the cytoplasm of an enucleated egg that the genetic material has been removed. The membranes of the blastomere and an enucleated egg are fused together artificially.

blastocyst is converted into a tissue culture to make a stem cell line for research or clinical application.<sup>5</sup>

Current controversy about the creation of a "human clone" concerns the possibility of replicating a human being (living or deceased) through the somatic cell nuclear transfer (SCNT) technique used to create Dolly the sheep, but as analyzed by the World Health Organization (WHO), the term is used in several other ways:

[F]irst, "human clone" can also be applied to the creation of genetically identical siblings, such as those which occur naturally in identical twins or artificially through the splitting of embryos in the laboratory at the two to eight cell stage of development (sometimes called "pre-embryo"). Embryo-splitting has been used for some time in artificial breeding programs for farm animals like cattle. In a 1993 experiment, scientists in Washington, D.C, turned 17 human embryos into 48. These embryos (which had been chosen for research because they were considered non-viable) were cultured for some days and then discarded. If viable embryos created through such splitting were implanted and brought to term simultaneously in the same uterus, they would be comparable to monozygous twins. If the blastomeres, i.e. the cells that result from the cleavage of a fertilized egg, were split and one of the resulting embryos were brought to term while the others were frozen (cryopreservation being a common technique in fertility clinics) and then implanted and born at a later date, the result would be "serial Although genetically identical, such individuals would differ from twins."

<sup>&</sup>lt;sup>5</sup> See Mahnoush H. Arsanjani, *supra*, note 2, at 164 Fn. 2 While pioneer cloning experimentation goes back to the early 1950s, it was in the 1970s that it acquired its contemporary meaning, namely, "any artificial, identical genetic copy of an existing life form." See UNESCO, HUMAN CLONING: ETHICAL ISSUES, 7 (2d rev. ed., 2005), also available at http://unesdoc.unesco.org/ ulis/index.html

ordinary twins because they would be born at different times (and perhaps even to different mothers); moreover, the decision to implant the later-born serial twin(s) might be based on evaluating the "fitness" or other characteristics of the first-born, and predictions about the life course of the later-born twin(s) might be based on experience with the pre-existing one.

The term "human cloning" can also be applied to the creation of embryos through SCNT not to produce offspring but for use as a scientific tool. In particular, such non-reproductive use of cloning — sometimes termed "research cloning" or "therapeutic cloning" to differentiate it from cloning for reproductive purposes — is being pursued as a means of creating human embryonic stem cells for scientific study and eventually for therapeutic purposes. Once cloned embryos have reached the blastocyst stage (approximately 5 days after fertilization), the inner cell mass, from which stem cell lines are derived, is removed; in the process, the embryo is destroyed. Some scientists engaged in this work prefer to describe it using the term "cloning" connotes the creation of a child. Critics of this position say that "cloning" is the appropriate term because the suggestion that the procedures differ is spurious; it is better to say that the same technique — the creation of embryos through SCNT — can have two different outcomes, the production of embryonic stem cells and the production of babies.<sup>6</sup>

The Canadian Assisted Human Reproduction Act of 2004 is an example of post-Dolly national legislation of this type. Under this Act, the creation and implantation of a "human

<sup>&</sup>lt;sup>6</sup> See WORLD HEALTH ORGANIZATION (WHO), A Dozen Questions (And Answers) on Human Cloning, at http://www.who.int/ethics/topics/cloning/en/

clone" are prohibited. The definition of "Human clone" clearly captures somatic cell nuclear transfer (SCNT) technique as follow:

[A]n embryo that, as a result of the manipulation of human reproductive material or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single – living or deceased – human being, foetus or embryo.

For the purpose of this dissertation, cloning refers to any processes that result in the creation of an identical or nearly identical genetic copy of a DNA molecule, a cell, a plant, an animal or a human being. It is different from natural fertilization, which "sexually" reproduces an embryo.<sup>7</sup> With respect to human cloning, it is a type of "asexual" reproduction, which means reproduction not initiated by the union of egg and sperm, but associated with a technique called "somatic cell nuclear transfer (SCNT)." The practice of this technique takes the nucleus from a body cell and transfers it into a female egg that has had its nuclear material removed. With an electric current or chemical stimulus the cloned embryo begins to divide, as does a sexually fertilized embryo.

Typically there are two applications of this technique with a critical distinction. Reproductive cloning or so-called adult DNA cloning, using somatic cell nuclear transfer involves creating a cloned embryo, and subsequently implanting that embryo into the uterus with

<sup>&</sup>lt;sup>7</sup> For example, in natural fertilization the developing human embryo has the genetic makeup or DNA of both parents' 23 chromosomes from the female and 23 from the male. The embryo is the unique human organism with a novel genetic makeup having the full potential to develop to adulthood. See generally, What Is Cloning, at http://robby.nstemp.com/index.html

the objective of creating a new life. The goal of this technique is to produce a clonal embryo, which is implanted in a female's womb with the intent of creating a fully formed living body almost genetically identical to the DNA donor.<sup>8</sup>

On the other hand, therapeutic cloning, or so-called biomedical cloning, involves the creation of a cloned embryo used to derive stem cells or tissues after the embryo is grown to a fatal stage for transplantation. Stem cells are primordial cells capable of developing into a variety of types of cells and have potential to grow in to any tissue or organ in the body. Instead of being implanted in a female's womb and brought to term, the goal of this technique is to generate stem cells with healthy genes and culture them in petri dishes with the intent of providing replacement tissue and organs for the patient who has defective genes or damaged tissue and organs. Since the cloned embryo would contain DNA coming from the donating patient, the cloned tissue and organs would be compatible with the patient's immune system. Therefore, the operation of the transplantation of tissue and organs back in to the DNA-donating patient would not have to be accompanied by any anti-immunity drug or device.

Scientists have also attempted other kinds of research on cloned embryos. In consideration of the moral value and dignity of a human being, notwithstanding the purpose of

<sup>&</sup>lt;sup>8</sup> In fact these techniques do not provide exact cloned – they would be 99.7% identical to the DNA donor. This is because some important genes, which are present outside the nucleus in mitochondrion, are contributed by the egg cell. See generally, at http://nostalgia.wikipedia.org/wiki/Human\_cglonin

any giving cloning research, if the process is accomplished through a human somatic gene or cell nuclear transfer technique, then it must be regarded as human cloning technology and deserve to incur serious moral and legal observations as well. Thus, a hybrid animal-human nuclear transfer that implants human genetic material or cell nuclear into an animal egg to create a cloned embryo would also be subject to rules governing human cloning technology. All kinds of these researches are highly controversial from a variety of viewpoint in either domestic or international laws.

Since the human reproductive process may be considered a form of genetic engineering and the use of embryonic stem cells may result in the destruction or manipulation of human embryos, human cloning technology and stem cell research may both be deemed notoriously controversial from the perspectives of law and ethics. These life science developments involve not only major human and fundamental rights issues, but also religious and ethical considerations. Might we supersede God's role to clone lives? Should we enrich human lives at the expense of ignorance of our common good or so-called "consciousness?" Can laws or regulations step into this newly developed scientific sphere today? Even more, from an international overview, will the respective interests of law, ethics, and science be universally compromised in some way or in some sense? These problems have not yet been properly clarified in many aspects and need our further attention through advanced study and analysis. On 8 March 2005, the Declaration on Human Cloning was adopted by the General Assembly of the United Nations by a recorded vote of eighty-four to thirty-four, with thirty-seven abstentions.<sup>9</sup> The Declaration concluded an effort that had originated in 2001 with a proposal by France and Germany for a convention against reproductive cloning of human beings. Despite recalling the major purpose and intent of the Universal Declaration on the Human Genome and Human Rights (UDHGHR) adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) on 11 November 1997,<sup>10</sup> it declares that all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life shall be prohibited.

Although the Declaration may still be subject to various interpretations, the United States and eighty-three other member nations positively support a ban on all human cloning technology, both for reproductive and experimental or therapeutic purposes. Based on this international instrument, it seems that the majority of member nations in the United Nations are not inclined to give permission to these evolutionary techniques in any sense.<sup>11</sup>

<sup>&</sup>lt;sup>9</sup> See United Nations Declaration on Human Cloning, A/Res/59/280 of 8 March 2005

<sup>&</sup>lt;sup>10</sup> See UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION (UNESCO), RECORDS OF THE GENERAL CONFERENCE, Twenty-ninth Session, Paris, 21 October-12 November 1997, vol. 1: Resolution, resolution 16

<sup>&</sup>lt;sup>11</sup> See generally, U.S. Position Paper: Human Cloning, August 2003, at http://www.un.int/usa/cloning-paper-print.htm

However, the United Kingdom and thirty-three other member nations have given permission to clone human embryos for therapeutic but not reproductive purposes. Furthermore, some scientists claim that human cloning technology is expected to result in several miraculous medical breakthroughs. They say that through current reproductive technologies *in vitro* fertilization (IVF), a cloning procedure by which an egg minus its DNA is mixed with another cell to form an embryo and implanting the cloned embryo into a uterus is not technically impossible.

Those who advocate human cloning also insist that, based on the fundamental freedom of reproduction, people should have a right to clone themselves, in the same way that they have a right to utilize natural or other reproductive-related technologies and procedures such as assisted reproductive technique (ART) and *in vitro* fertilization (IVF) to reproduce their own heirs and offspring. The government should not be allowed to tell people what they can or cannot do when the action in question comes to reproduction-related matters. The anti-cloning law may underestimate possible benefits and overstate feared risks of the human cloning technique.

From this viewpoint, the reaction of international law to human cloning technology involving human somatic cell nuclear transfer reflects no legal but an ethics dominated view. However, any blending of moral and legal issues may result in extraordinary ambiguity in terms and conditions of any forms of legal instruments. Emotional opinions or predetermined notions may also be poured into them through political processes at either international or domestic level. As a result, the effectiveness and clarity of such legal instruments may therefore be limited and restrained. Thus, weighing the nature and function of law and morality may be important if the international community has gone forward to impartially deal with such exclusive fruits of life science technology as human cloning here.<sup>12</sup>

Since a variety of opinions exist among many nations and scholars as to the ethical and scientific value of contemporary cloning technology, this research will focus on several pro and con arguments about moral, ethical, legal, and policy issues of cloning which affect mankind under the current international legal regime. If someday human cloning technology were safe and widely available, what kind of uses would people find for it and why?

## III. Methodology and Research Structure

In the analysis that follows, it will emphasize significant legislations and documents as well as important reports that have regulated or recommended a ban or an approval of any kind of cloning which may affect essential rights or interests of human beings. A serious assessment of human welfare and the importance of public interest for and against human cloning will also

<sup>&</sup>lt;sup>12</sup> Regarding Pro-cloning related information, see generally, at http://www.humancloning.org/

be reviewed. In addition, views and opinions of some outstanding scholars and experts in fields of law, medicine, religion, ethics, and science will of course be the primary foundation for this research, hopefully inspiring an unbiased and constructive path for readers.

Due to the complicated character of this research topic, the methodology adopted here will mainly be case-review and article-analysis. With a comparative sense, this research will first accumulate and read related laws, cases, and articles, then analyze the issues in question and examine the possible approaches to properly resolve the involved disputes. No matter what community we inhabit, the need for scientific development and the imperative of ethical conduct should be seriously weighed and balanced by a neutral and unbiased legal system.

The research structure for this dissertation is comprised of seven parts. Introduction -Explains the original intent and purpose, the methodology employed, and the expected effects and benefits of this research. Chapter 1: Human Cloning: A Breakthrough Technology with Great Hope but Less Faith – Reviews current human cloning technology and its situations. Chapter 2: Ethical and Religious Concerns on Human Cloning Technology - Examines important ethical and religious concerns in contemporary cloning procedure substantially relating to humans. Chapter 3: Legal and Policy Aspects on Human Cloning Technology – Explores important legal and policy issues of current cloning technology for either reproductive or therapeutic purposes. Chapter 4: Safeguard Rights and Liberties Essential to the Future of Humanity in the Cloning Age – Regards essential rights and liberties needed to be safeguarded by the State at current emergence of human cloning technology. Chapter 5: Regulatory Consensus on Human Cloning Technology in the International Community - Analyzes the regulatory standards within the international community for preservation of human dignity and human rights involved in current human cloning technology. Conclusions and Recommendations – Considers appropriate and effective norms for the international community to consensually oversee and sustain the development of future human cloning technology.

# <u>Chapter 1</u>

# <u>Human Cloning: A Breakthrough Technology with Great</u> <u>Hope But Less Faith</u>

## I. Introduction

Cloning is not just about science fiction but offers more than merely theoretical benefits. It is a real and novel technology that can provide dramatic advantages to the human kind in the years to come. Although cloning is a natural part of agriculture and plant life, scientists is always looking to improve on nature and have come up with ways which combine with bioengineering techniques to produce clones more efficiently. Scientists can genetically engineer a plant to have a particular characteristic by inserting a gene into it. For example, by inserting a gene into soybeans, they would have a particular helpful characteristic to be resistant to a certain disease. They can thus clone the soybeans using this technique and grow it that way. In addition, animals can also be treated with bioengineering techniques to be better suited to farming. For example, by giving a gene that produces a protein called lysostaphin, a cow would have been protected against mastitis disease that stops a cow from producing milk by destroying the cow's milk-secreting cells in its udder. The cow can then be cloned and mass-produced if it is proved to be resistant to mastitis.

Since animal cloning has produced some remarkable results within the last few years, it has suggested to some extent that there should be a way to produce a human clone in the near future. While there has been no substantiated evidence for the cloning of humans, recent successes in deviation of stem cells from human embryos have amplified concerns that the development of human cloning technique is not beyond the realm of possibility. Many news articles have appeared recently highlighting the potential to clone a human baby in order to replace a loved one who died as a newborn. However, a lot more social, moral, and ethical arguments have also been raised in opposition to clone humans.

It is indisputable that currently cloning technology is in its infancy. Since 1997 when Dolly the Sheep was produced, gradual improvements in cloning technology have enable researchers to generate mouse, cattle, goat, pig, deer, rabbit, cat, mule, horse, and dog clones, but animal cloning remains extremely inefficient. It is reasonable for the public to conclude that future human cloning will have the similar situation, as does animal cloning. However, in spite of the public outrage against the feasibility of human cloning technology, researches in areas such as embryonic stem cells for the repair of damaged or degenerated human organs and tissues could still be positively observed. These kinds of researches are intended to develop reprogramming of certain cells to turn into specific tissues types, which could regenerate nerve, muscle, and other cell types, alleviating Parkinson's, Alzheimer's, heart disease, diabetics, and some other chronic illnesses. Therefore, the potential benefits of so-called therapeutic stem cell cloning seem to be enormous, and researches in this field should not be weighed down.

This chapter will review critical milestones, which led to establish current cloning technology in the history of science and biology. Appropriate definitions and scopes of related terms for the purpose of this research dissertation, such as cloning, cloning technology, human cloning, and stem cell research, will also be carefully described here. In addition, it will give intensive concerns to the relationship between stem cell research and human cloning. It will look to how scientists work with embryonic and adult stem cells for the human good, the appropriateness of narrow-tailored human cloning technology, and try to distinguish the potential benefits and disadvantages of this kind of technology for the human being. Since this dissertation will focus on its effort on human cloning technology, the plant or animal cloning will be reviewed only when it is related to the institution of the idea and strategy of human cloning.

## II. Cloning Technology: The Past, Present and Future

Nature has been busy in cloning organisms for a long time, but only in more recent times has man gotten into the act. The astonishing breakthrough was when Dolly the Sheep was cloned in 1997. However, plants have been cloned for agricultural purposes for thousands of years. Basically, cloning is different from natural fertilization, which is sexual reproduction that occurs when a sperm fertilizes an egg. In normal fertilization the developing embryo has the genetic makeup or DNA of both parents: twenty-three chromosomes from the female and twenty-three from the male. The embryo is the unique organism with a novel genetic makeup having the full potential to develop to adulthood.

Cloning, on the other hand, is a type of asexual reproduction, which is not initiated by the union of egg and sperm. Cloning a gene means to extract a gene from one organism and to insert it into a second organism; cloning an organism means to create a new organism with the same genetic information as an existing one. This can be done by removing the nucleus from an egg cell and replacing it with a nucleus extracted from some cell of the organism to be cloned. This technique has been successfully performed on several species since Dolly. Many people believe that attempts to perform human cloning would be unsafe and unethical, but some scientists have publicly announced their intention to do so.<sup>13</sup>

<sup>&</sup>lt;sup>13</sup> See generally, What Is Cloning? at http://robby.nstemp.com/index.html

#### A. What is Cloning Technology?

The word "Clone," derives from the Greek word "klon" refers to asexual reproduction for "twig" or "shoot." However, it is a simple word with a lot of particular meanings.<sup>14</sup> Identical twins in humans are clones of one another. When plants like potatoes send out runners, modified versions of a stem, new plants grow wherever the runners take root. Each new plant is a clone of the original. Certain animals like the hydra can clone themselves when a small part of their body is cut off. Even higher-level animals, such as certain insects, worms, and some species of lizards, fish, and frogs, can under certain conditions or environments to a certain extent clone themselves through a process called parthenogenesis. They can develop into adults from unfertilized eggs. These developed animals will get genetic material only from the mother, and none from the father. Not surprisingly, the nature has successfully created clones for millions of years. Cloned molecules, cells, plants, and animals are all generally identical copies produced without any intervention from the sexual process.

Furthermore, the term "cloning" is used to describe many different processes that involve making copies or duplicates of biological material with the range from a short section of the

<sup>&</sup>lt;sup>14</sup> The definition of a "clone" to be in four parts: "(1) A group of genetically identical cells descended from a single common ancestor, such as a bacterial colony whose members arose from a single original cell as a result of binary fission; (2) An organism descended asexually from a single ancestor, such as a plant produces by layering or a polyp produced by budding; (3) A replica of a DNA sequence, such as a gene, produced by genetic engineering; (4) One that copies or closely resembles another, as in appearance or function." See "Cloning," in AMERICAN HERITAGE DICTIONARY

DNA polymer to an entire nucleus or genome through some natural or artificial ways. In other words, cloning is the creation of an organism that is an exact genetic copy of another.<sup>15</sup> This means that every single bit of DNA is the same between the two. In most cases, isolated genes or cells are artificially duplicated primarily for the use of scientific study and medical research, and no new animals are purposely created by any man's act. However, the experiment that led to the cloning of Dolly the Sheep in 1997 was different and much controversial. It used a cloning technology called somatic cell nuclear transfer and resulted in an animal that was a genetic twin of an adult sheep. The cloning technology may also be used to produce an embryo from which cells called embryonic stem (ES) cells. They could be extracted to use in research into potential therapies for a wide variety of diseases.<sup>16</sup>

#### 1. Cloning Before 1950s

We may have first heard of cloning when Dolly the Sheep showed up on the scene in 1997, cloning technologies have been around for much longer than Dolly, though. The history of cloning technology should be dated back to 1891 when Hans Driesch separated the blastomeric of a cleaving sea urchin egg in a contentious experiment in Naples. He picked sea urchins because they have large embryo cells, and grow independently of their mothers. Dreich took a

<sup>&</sup>lt;sup>15</sup> The definition of "cloning" to be: "The making of identical copies of molecules, cells, tissues, and even entire animals." See National Bioethics Advisory Commission (NBAC), *Cloning Human Beings*, in REPORT AND RECOMMENDATIONS OF NATIONAL BIOETHICS ADVISORY COMMISSION 33 (June 1997), also available at http://bioethics.gov/

<sup>&</sup>lt;sup>16</sup> See Kathi E. Hanna, *Cloning / Embryonic Stem Cells*, at http://www.nlm.nih.gov/

two-celled embryo of a sea urchin and shook it in a beaker with full of sea water until the two cells separated. Each grew independently, and formed a separate whole sea urchin.<sup>17</sup>

In 1899, Jacques Loeb and Gregory Pincus were experimenting with another reproductive technique – artificial parthenogenesis. Loeb found that by treating sea urchin eggs with appropriate inorganic salt solutions, an embryological development, a process that up to the time had required the sperm of the male sea urchin, could be initiated. He thus announced that physical chemistry or other inducers could be tool for altering the basic process of reproduction.<sup>18</sup> In 1937, Pincus also alleged that he produced a rabbit by parthenogenesis technique.<sup>19</sup>

In 1902, German embryologist Hans Spemann separated a two-celled embryo of a salamander, which also grew externally. He later separated a single cell from a sixteen-celled embryo. In these experiments, both the large and the small embryos developed into identical adult salamanders. To prove his theory that no genetic material would be lost as cells grew and divided, Spemann went on to propose what he called a "fantastical experiment" in 1938. This

<sup>&</sup>lt;sup>17</sup> See DRIESCH, HANS, (see also Adolph Eduard Driesch) DICTIONARY OF SCIENTIFIC BIOGRAPHY, CHARLES COULSTON GILLISPIE, v.4, p.187a (Charles Scribner's Sons, eds., 1980)

<sup>&</sup>lt;sup>18</sup> See LOEB, JACQUES, DICTIONARY OF SCIENTIFIC BIOGRAPHY, CHARLES COULSTON GILLISPIE, v.8, p.446a (Charles Scribner's Sons, eds., 1980)

<sup>&</sup>lt;sup>19</sup> See Suzanne M. Rini, Behind and Beyond the Cloning Event of 1993, at http://www.all.org/

experiment was anticipated to successfully remove the genetic material from an adult cell, and use it to grow another adult.<sup>20</sup>

#### 2. Cloning After 1950s

There were no major advances in cloning technology until November of 1951, when a team of American scientists in Philadelphia working at the lab of Robert Briggs and T. J. King at Indiana University cloned a frog embryo. This team did not simply break off a cell from an embryo. Instead, they took the nucleus out of a frog embryo cell and used it to replace the nucleus of an unfertilized frog egg cell. Once the egg cell sensed that it had a full set of chromosomes, it began to divide and grow.<sup>21</sup> In 1966, British cell biologist John B. Gurdon at Oxford University spent a lot of time experimenting to achieve normal cloned frogs from adult cells. Although seven hundred and seven attempts produced eleven clones, the frogs did not develop beyond tadpoles.<sup>22</sup>

Many experiments involving plants and animals embryos have been substantially performed in 1970s. In 1984, Dr. Steene Willadsen announced that he had successfully transferred nuclei from embryos of sheep to produce clones. He was also successful with cows and monkeys. He advanced his methods and began cloning embryos that were in the 64-128

<sup>&</sup>lt;sup>20</sup> See Spemann, Hans, Dictionary of Scientific Biography, Charles Coulston Gillispie, v.12, p.568a (Charles Scribner's Sons, eds., 1980)

<sup>&</sup>lt;sup>21</sup> See Think Quest, *History of Cloning*, at http://www.thinkquest.org/library/search.html

<sup>&</sup>lt;sup>22</sup> See VANCE PACKARD, THE PEOPLE SHAPERS 273 (Little Brown & Co., 1977)

stages. This suggested that perhaps nuclear transfer was possible with differentiated cells. In 1994, Dr. Neal First produced cows by nuclear transfer from more developed embryos. He produced four calves. Two years later, Dr. Ian Wilmut and Dr. Keith Campbell of Roslin Institute in Edinburgh, Scotland produced Megan and Morag, which were cloned sheep from embryo cells. By those dates, cloning technologies utilized for the purpose of duplicating an animal, plants, or any other organism included embryo splitting, embryo transfer, gene transfer, nuclear transfer, and certain chimera production.<sup>23</sup>

#### 3. Cloning Follows Dolly

On 23 February 1997 Dr. Ian Wilmut succeeded in cloning a sheep from a single adult sheep cell. Dolly, the sheep that was created in this manner, is genetically identical to the adult sheep from which she was cloned. Soon after that date, on 2 March 1997 scientists at the Oregon Regional Primate Research Center in Beaverton, Oregon, reported cloning two monkeys. The monkeys, born in August 1996, were cloned from monkey embryo cells, not cells from an adult monkey. The cloned primates were not genetically identical to any adult monkey.

On 18 December 1997 Roslin Institute scientists reported data showing the production of the world's first lambs that carry a human gene (transgenic lambs) created by nuclear transfer. To produce the lambs, they first exposed skins cells (fibroblast) to DNA that included a human

<sup>&</sup>lt;sup>23</sup> See J.N. Shelton, *Embryo Manipulation in Research and Animal Production*, AUSTRALIAN JOURNAL OF BIOLOGICAL SCIENCE (1988)

gene and a marker gene. Then they took the cells that contained both the marker gene and the human gene and followed the same cloning technique they used to make Dolly. Both lambs contained the transgenic gene in their cells.<sup>24</sup>

In July of 1998 researchers at the University of Hawaii announced that they had created dozens of mice by cloning, using a new technique in the most commonly-used laboratory animal. The researchers were able to reprogram nuclei from cells taken from ovaries of adult mice. Known as cumulus cells, these differentiated cells surround the eggs of mice, as well as humans, and are shed with eggs during ovulation. For the cloning experiment, nuclei from cumulus cells were inserted directly with egg cells whose nuclei had been removed. The combination was then activated with chemicals prompting the eggs to start dividing and form embryos. The embryos were transferred to the wombs of surrogate mice, and some resulted in the birth of mice clones that were identical to mice from which the cumulus cells were taken. This was the first published report that adult animals could be cloned since the announcement of the birth of Dolly by researchers in Scotland.<sup>25</sup>

In January of 2000, Dr. Gerald Schatten and his colleagues at the Oregon Regional Primate Center, Beaverton, Oregon, announced the first successful example of the cloning of a monkey by using embryo splitting technique. Some scientists hope that embryo splitting can be

 <sup>&</sup>lt;sup>24</sup> See Mary V. Wright, *Cloning: A Select Chronology*, 1997-2003, in REPORT OF CONGRESS (2003)
 <sup>25</sup> Id.

used to develop genetically identical laboratory animals better suited for testing therapies that may eventually be used to treat humans. In March, researchers at the Blacksburg, Virginia, facility of PPL Therapeutics announced the production of the first cloned pigs with the cloning technique used to create Dolly and some additional inventive steps. Researchers hope that cloned pigs can eventually become a source of organ and cell transplants for humans.<sup>26</sup>

In July of the same year, Alexander Kind and his colleagues at PPL Therapeutics in Scotland announced that they had successfully cloned three transgenic lambs which were the first transgenic livestock to carry specifically chosen modifications in their genes. The inserted gene allowed the sheep to produce the human protein alpha 1-antitrypsin in their milk. This protein may someday be used to treat a variety of lung diseases, including cystic fibrosis. Another potential application of this technique is the development of animals that could supply organs for human patients.<sup>27</sup>

In January of 2002, researchers at Advanced Cell Technology in Worcester, Massachusetts, announced that they have used cells derived from cloned cow embryos to grow functioning kidney-like organs that were not rejected when implanted into adult cows, marking the first use of cloning technology to grow personalized, genetically-matched organs for transplantation. This may lead a presumption that cells taken from the human patient would be

<sup>&</sup>lt;sup>26</sup> Id.

<sup>&</sup>lt;sup>27</sup> Id.

used to produce a cloned human embryo genetically identical to the patient. The experimental procedure would then harvest cells from the embryo to grow the organs needed for transplant, which theoretically would not be rejected by the patient because they would be genetically identical. In addition, in March, French researchers led by Jean-Paul Renard at the National Institute for Agronomical Research outside Paris also reported that they had cloned rabbits by using genetic materials from adult cells. The French team is collaborating with other scientists to try to clone rabbits with the gene defect responsible for cystic fibrosis in human beings.<sup>28</sup>

## **B.** Leading-Edge Cloning Technologies

"Cloning technology" refers to different cloning procedures with different goals. Deoxyribonucleic Acid (DNA) cloning or so-called molecular cloning or gene cloning, is a molecular biological technique, which transfers a DNA fragment of interest from one organism to a self-replication genetic element such as a bacterial plasmid. To clone a gene, a DNA fragment containing the gene of interest is isolated from chromosomal DNA using restriction enzymes and then united with a plasmid that has been cut with the same restriction enzymes. When the fragment of chromosomal DNA is joined with its cloning vector in the lab, it is called a recombinant DNA molecule. Following introduction into suitable host cells, the recombinant

<sup>&</sup>lt;sup>28</sup> Id.
DNA can then be reproduced along with the host cell DNA. This cloning technique has been utilized since the 1970s, and it has become a common practice in molecular biology labs today.<sup>29</sup>

#### 1. Embryo Splitting Cloning

Embryo splitting cloning is a medical technique, which produces monozygotic, or identical twins or triplets. It duplicates the process that the nature uses it to produce twins or triplets. In this procedure, one or more cells are removed from a fertilized embryo and stimulated to develop into one or more duplicate embryos. Twins or triplets are thus formed, with identical DNA. This cloning technique has been utilized for many years on various species of animals, but only very limited experimentation has been done on humans.<sup>30</sup>

#### 2. Reproductive Cloning

Reproductive cloning is a biological technique, which is intended to produce a duplicate of an existing animal. In this procedure, the nucleus or DNA from an ovum or an egg is removed and replaced with the nucleus or DNA from a somatic cell removed from an adult animal. Unlike sexual reproduction in which a new organism is formed when the genetic material of the egg and sperm fuse, there is only a single parent in this nuclear transplantation cloning procedure. The fertilized ovum or zygote, which is called a pre-embryo, is implanted in

<sup>&</sup>lt;sup>29</sup> See generally, Human Genome Project Information, 20 February 2006, at http://www.ornl.gov/hgmis/

<sup>&</sup>lt;sup>30</sup> See Bruce A. Robinson, *Human Reproductive and Therapeutic Cloning*, in ONTARIO CONSULTANTS ON RELIGIOUS TOLERANCE, at http://www.religioustolerance.org/cloning.htm

a womb and allowed to grow into a new animal. This technique also differs from previous embryo cloning technique because it does not involve an existing embryo. Dolly the Sheep was produced in 1997 all the way through this nuclear transplantation cloning procedure.

Since Dolly was cloned, this cloning technique has been used to produce other mammals, such as mice, goats, pigs, cows, rabbits, cats, monkeys, and dogs. All these clones were created using nuclear transfer technology. There have been attempts with other animals, including chickens, horses, wild cats, and a rare species of wild ox, but these clones either did not survive to birth or died not long after birth. These results point out one of the big problems in reproductive cloning, i.e., most clones don't survive and it is unsafe to be a clone.<sup>31</sup> The process of stripping the nucleus from an egg cell and replacing it with the nucleus of a donor cell is a traumatic one, and improvements in cloning technologies may be needed before many species can be cloned successfully. Furthermore, based on the progress of previous animals study, it unsubtly has the potential of producing a twin of an existing human. The unsafe and uncertain characters of reproductive cloning make the prospect of applying this technique in humans very unpredictable and specifically banned by the international community or strictly forbidden by the law in many countries.

## 3. Therapeutic Cloning

<sup>&</sup>lt;sup>31</sup> See DAVID A. PRENTICE, STEM CELLS AND CLONING 23 (Benjamin Cummings, 2003)

Therapeutic cloning is a biomedical technique, which is intended to produce human embryos for use in research and then to develop a healthy copy of a sick person's tissue or organ for medical treatment and transplantation. The goal of this technique is not to create a cloned animal or human being, but rather to harvest stem cells that can be used to study for human good and to treat disease. The initial stages in this procedure are identical to those in reproductive cloning, however, the stem cells are removed from the pre-embryo and encouraged to develop tissue or a whole organ for transplanting back into the person who supplied the DNA. Since the tissue or organ would have the sick person's original DNA, there would not be any danger of organ rejection. Therefore, it might be anticipated that the patient would not have to take immunosuppressant drugs for the rest of their life.

Therapeutic cloning technology may someday be used in medical therapies to produce whole organs from single cells or to produce healthy cells that can replace damaged cells in degenerative diseases such as Alzheimer's, Parkinson's, diabetes, and so on. However, much work still needs to be done before therapeutic cloning can become a realistic option for the treatment of disorders.

## C. Human Cloning and Its Related Technologies

On the basis of (1) a careful analysis of the act of cloning, and its relation to the means by which it is accomplished and the purposes it may serve, and (2) an extensive critical examination of alternative terminologies, "Human cloning" and its related technologies defined by the Report of The President's Council on Bioethics, inquired by the U.S. former President George W. Bush, as follows:

[H]uman cloning: The asexual production of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing or preciously existing human being. It would be accomplished by introducing the nuclear material of a human somatic cell (donor) into an oocyte (egg) whose own nucleus has been removed or inactivated, yielding a product that has a human genetic constitution virtually identical to the donor of the somatic cell. (This procedure is known as "somatic cell nuclear transfer" or SCNT). We have declined to use the terms "reproductive cloning" and "therapeutic cloning." We have chosen instead to use the following designations:

Cloning-to-produce-children: Production of a cloned human embryo, formed for the (proximate) purpose of initiating a pregnancy, with the (ultimate) goal of producing a child who will be genetically virtually identical to a currently existing or previously existing individual.

Cloning-for-biomedical-research: Production of a cloned human embryo, formed for the (proximate) purpose of using it in research or for extracting its stem cells, with the (ultimate) goals of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases.

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Cloned human embryo: (a) A human embryo resulting from the nuclear transfer process (as contrasted with a human embryo arising from the union of egg and sperm). (b) The immediate (and developing) product of the initial act of cloning, accomplished by successful SCNT, whether used subsequently in attempts to produce children or in biomedical research.<sup>32</sup>

Due to the intrinsic limitations of human cloning technology, some widely mentioned undesirable applications of cloning are impossible. Others, which may be possible technically, are still clearly prohibited by existing laws, public policies, and professional ethical standards. In order to clarify the numerous misconceptions about human cloning technology, it is essential that the public or international community should be helped become conscious about the intrinsic technical limits of human cloning as well as the moral imperatives and legal protections that should prevent abuses of this possibility-unlimited technology.

# III. Stem Cell Research: Closely Linked to Cloning Technique

Stem cell research and cloning technique are closely linked. Study of the medial or therapeutic applications to which stem cells can be put are relatively new, but many studies show

<sup>&</sup>lt;sup>32</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY xxiv (U.S. Government Printing Office, July 2002) Based on the meaning of human cloning prescribed above, the term "human cloning" is used in this dissertation to refer to all human cloning: cloning-to-produce-children (a.k.a. reproductive cloning) and cloning-for-biomedical-research (a.k.a. therapeutic cloning). Human embryonic cloning, accomplished by successful SCNT, is also considered human cloning here.

a wide variety of potential benefits. A new era in stem cell biology began in 1998 with the deviation of cells from human blastocysts and fetal tissue with the unique ability of differentiating into cells of all tissues in the organism or body. Generally speaking, there are four sources of human embryonic stem (ES) cells: cadaveric fetal tissue, embryos remaining after infertility treatments, embryos made solely for research purposes using *in vitro* Fertilization (IVF), and embryos made using somatic cell nuclear transfer (SCNT) into oocytes. Each source of material raises ethical questions as well as scientific, medical, and legal ones. The resolution of these ethical and scientific issues depends to some degree on the source of the stem cell.

Since then, several research teams have portrayed many of the molecular characteristics of these cells and improved the methods for culturing them. In addition, scientists are beginning to direct the differentiation of the human pluripotent stem cells and to identify the functional capabilities of the resulting specialized cells. Although in its earliest phases, research with these cells is proving to be important to developing innovative cell replacement mechanism to reconstruct tissues and reinstate critical functions of the diseased or damaged human body.

Somatic cell nuclear transfer (SCNT) holds great potential to someday create medically useful therapeutic products. Human embryonic stem (ES) cell preparations could potentially be produced by using the somatic cell nuclear transfer (SCNT) to produce a cloned human embryo. The cloned human embryo can then be taken apart at the blastocyst stage and the stem cells can subsequently be isolated. These stem cells would be genetically virtually identical to cells from the nucleus donor, and thus could potentially be of great value in biomedical research. Most researchers also believe that it will yield very useful and important knowledge, pointing toward new therapies and offering one of several possible routes to circumvent the immune rejection problem.<sup>33</sup>

# A. What are Stem Cells?

Many people had not heard about stem cells until 1998, when Dr. James Thomson of the University of Wisconsin at Madison first isolated human embryonic stem cells from the inner cell mass of the early embryo, which is called the five-day-old blastocyst, from *in vitro* fertilization (IVF) clinics, and developed the first human embryonic stem cell lines. At the same time, Dr. John Gearhart of John Hopkins University reported the first derivation of human embryonic germ cells from an isolated population of cells from two-to-four-month-old fetuses in gonadal tissue, which is known as the primordial germ cells and destined to become the eggs and sperm. The cells obtained from the blastocyst are embryonic stem (ES) cells, whereas the cells obtained from the fetuses are embryonic germ (EG) cells.<sup>34</sup> From both of these sources, the

<sup>&</sup>lt;sup>33</sup> Id., at xxvi

<sup>&</sup>lt;sup>34</sup> See JOSEPH PANNO, STEM CELL RESEARCH: MEDICAL APPLICATIONS & ETHICAL CONTROVERSY 18 (Facts on File, Inc., 2005)

researchers developed pluripotent stem cell lines, which are capable of renewing themselves for long periods and giving rise to many types of cells or tissues.<sup>35</sup>

Plainly speaking, stem cells are primordial cells capable of developing into a variety of types of cells. <sup>36</sup> They may be found in very early embryos, as mentioned before, or in the adult organism or body. Because stem cells can rapidly divide from one to another, they can be cultured through *in vitro* fertilization (IVF) in laboratory petri dishes. They are capable of continually reproducing themselves and serve to renew tissue throughout an individual's life. Even more, since most of stem cells may differentiate into all cell types in the body, they could theoretically be used to replace damaged or diseased tissues and cure a wide variety of diseases.<sup>37</sup> A number of biotechnology companies worldwide are now developing products arising from newly discovered technologies that exploit the therapeutic potential of stem cells.

# 1. Stem Cells from Embryos

Scientists often distinguish between different kinds of stem cells depending upon their origin and their potential to differentiate. There are two general different kinds of stem cells, i.e.,

<sup>&</sup>lt;sup>35</sup> See The National Institutes of Health, *Stem Cells: Scientific Progress and Future Research Directions*, in REPORT BY THE NATIONAL INSTITUTES OF HEALTH 4 (University of the Pacific Press, 2005) (2001)

 $<sup>^{36}</sup>$  Id., at 1 "Stem cell" refers to "[A] cell that has the ability to divide (self-replicate) for indefinite periods – often throughout the life of the organism. Under the right conditions, or give the right signals, it can give rise (differentiate) to the many different cell types that make up the organism. It has potential to develop into mature cells that have characteristic shapes and specialized functions, such as heart cells, skin cells, or nerve cells."

<sup>&</sup>lt;sup>37</sup> See Association of Reproductive Health Professionals, Human Cloning and Genetic Modification: The Basic Science You Need to Know, at http://www.arhp.org/genetics/

stem cells from an embryo, and stem cells from an adult organism or body. There are three types of stem cells that can be harvested from embryos, e.g., pluripotent stem (PS) cell, embryonic stem (ES) cell, and embryonic germ (EG) cell.

Pluripotent stem (PS) cells only come from human embryos in the very earliest stages of development and from fetal tissue that would ultimately develop into the gonads.<sup>38</sup> Embryonic stem (ES) cells come from an embryo that is four to five days old, which is called the blastocyst. Cells from what is called the inner cell mass can be removed and cultured as embryonic stem cells. They can self-replicate and are pluripotent. Embryonic germ (EG) cells come from fetal tissue, especially from the area of the embryo that ultimately develops into the testes or ovaries. Since each type of stem cells can differentiate into any cell in the body, they hold out enormous promise and benefit for application to many medical or therapeutic actions.

### 2. Stem Cells in Adults

On the other hand, stem cells in adults are rare, difficult to isolate, purify, and grow. They can be found in some adult tissues, such as the bone marrow, brain, blood, cornea, and retina of the eye, liver, skin, and muscles among other tissues. Unlike embryonic stem cells,

<sup>&</sup>lt;sup>38</sup> See THE NATIONAL INSTITUTES OF HEALTH; *supra*, note 35, at 1-2. "pluri" – derived from the Latin *plures* – means several or many. Most scientists use the term pluripotent to describe stem cells that can differentiate into any type of cells derived from the three embryonic germ layers – mesoderm, endoderm, and ectoderm. The mesoderm is the middle germ layer of an embryo. It develops into tissues and structures including muscle, bone, skin, and tissue. The endoderm is the innermost germ layer of the embryo. It develops into portions of the digestive tract. The ectoderm is the outermost germ layer of the embryo. It develops into the nervous system, the outermost most layer of the skin, and the lining of body cavities such as the mouth.

they are unipotent and cannot normally differentiate into any type of cells in the body. They can only differentiate into the type of tissue where they are from. Thus, stem cells in the cornea cannot normally develop into nerve cells, and stem cells in the pancreas cannot normally develop into eye cells. They may only create replacement specialized cells for the tissues in which they are found.<sup>39</sup>

However, in the last several years, experiments have shown that under certain conditions, some adult stem cells can differentiate into tissues other than the ones in which they are found. The capability to do this is called plasticity. Experiments have shown that in the laboratory blood stem cells can be tricked into becoming neurons, and liver stem cells can produce insulin. All of these findings suggest that at least some stem cells are much more plastic than previously thought, which may have important implications for cell therapy. Although it is unclear how plastic adult stem cells can ultimately be, there is also potential for the medical or therapeutic application through stem cell cloning technique with less controversy.

## **B.** Therapeutic Cloning and Stem Cell Research

The phrase "therapeutic cloning" is frequently used, and almost as frequently misunderstood. It has nothing to do with cloning human beings or animals, and instead refers to

<sup>&</sup>lt;sup>39</sup> See DAVID A. PRENTICE, STEM CELLS AND CLONING 3-9 (Benjamin Cummings, 2003)

a kind of research and therapy using human stem cells for the human goods. In most general sense, therapeutic cloning refers to the general technique of gathering stem cells from an embryo or an adult, and inducing those cells to differentiate into specialized cells, with the hope of using those differentiated cells to cure or alleviate a disease or condition, for example to regenerate diseased heart tissue.

### 1. Cell Culture

Collecting human stem cells, whether from an adult or from an embryo, is just the first part in a long line of procedures that, hopefully, will lead to a treatment for a medical disorder. Once the cells are collected, they are grown in culture and stimulated in various ways to determine the types of cells they may differentiate. A technique known as cell culture grows cells in the laboratory, and it has been adapted to grow embryonic stem (ES) cells. Human embryonic stem cells are transferred to a culture dish that contains nutrients that the cells use in order to survive.

The embryonic cells grow in the dish, and after several days begin to proliferate enough so that they began to crowd the dish. Cells are then removed and dispersed to seed new culture dishes, where they grow, and when those dished become full, the cells are put into even more dishes. In this way, a large number of embryonic stem (ES) cells can be grown from just a few cells. After six months, for example, the original 30 embryonic stem (ES) cells that were taken from the inner cell mass of an embryo can grow into millions of cells.<sup>40</sup>

#### 2. Medical Benefits of Stem Cells

The hope for embryonic stem (ES) cells is that the large numbers of the cells can be grown and then given chemical and hormonal signals to specialize into a specific desired tissue. This might make it possible to use stem cells to create new cells and tissues on demand, to alleviate or even possibly cure a myriad of human diseases. In this way, specific nerve cells could be generated to implant into Parkinson's patients or different nerve cells for Alzheimer's patients or insulin-secreting pancreas cells for diabetics, or spinal cord neurons to repair spinal cord injury. Theoretically the possibilities are endless.<sup>41</sup>

Unlike embryonic stem (ES) cell, adult stem (AS) cells do not clump together and differentiate on their own in culture dishes. Tests have shown that when mouse adult stem cells are removed from the culture dish in which they are being grown, and injected into a mouse with a compromised immune system, tumors can develop. Unlike embryonic stem (ES) cells, adult stem (AS) cells do not proliferate to a great degree in culture dishes, and often do not proliferate at all. So it is much harder to get large quantities of these cells. They are apparently much less suited to study and for treating disease than are embryonic stem cells. However, adult stem cells

<sup>&</sup>lt;sup>40</sup> See JAY D. GRALLA & PRESTON GRALLA, UNDERSTANDING CLONING 94 - 95 (Alpha Books, 2004)

<sup>&</sup>lt;sup>41</sup> See DAVID A. PRENTICE, *supra*, note 39, at 9

do have one potential benefit. Because they are taken from an adult, if they are taken out of that adult's body and then later transplanted into the body, they will be less likely to be rejected by immune system of the body as foreign matter.<sup>42</sup>

It should be noted that at the present time, research cloning is not needed as a source of embryonic stem (ES) cells for medical purpose. Basic research questions about the therapeutic use of embryonic stem (ES) cells remain to be investigated. These studies do not require the use of human cloning technologies, since they can use human embryonic stem (ES) cells derived from *in vitro* fertilization (IVF) procedures. However, if researchers learn to produce therapeutic tissues or organs from human embryonic stem (ES) cells, then the issue of immune compatibility would have to be resolved.

In the event that therapeutic tissues have grown from stem cells, which were derived from clonal embryos created using cells from the recipient's body, they would probably not be rejected by the immune system of his or her body, either. Nevertheless, the feasibility of alternatives to using clonal embryos to prevent immune system rejection is still under examination. If the alternatives are technically and ethically possible, they would make it unnecessary to obtain the millions of human eggs that routine medical use of research cloning

<sup>&</sup>lt;sup>42</sup> SEE JAY D. GRALLA & PRESTON GRALLA, *supra*, note 40, at 94-95

would required, and would avoid some profound social consequences of cloning to certain extent.<sup>43</sup>

# IV. The Appropriateness of Human Cloning Technology

The possibility of human cloning technology to clone a human being dramatically increases after Scottish scientists at Roslin Institute created the well-known and much-celebrated sheep Dolly in 1997.<sup>44</sup> In 1998, Dr. Richard Seed, a Ph.D. from Harvard in nuclear physics, announced that he planned to set up a human cloning clinic to clone himself, his wife Gloria, implant cloned embryo into Gloria's womb so that she would bear her own cloned child as well. He also planned to clone humans to help infertile couples have children who would be genetically related to one of them and to replace a family member who died or was killed.

In 2002, the Raelians claimed that a baby called Eve had been cloned through their company Clonaid, headed by a French former racing car journalist Claude Vorilhon (who called

<sup>&</sup>lt;sup>43</sup> See CENTER FOR GENETICS AND SOCIETY, generally, *Research Cloning Frequently Asked Questions*, 30 June 2006, at http://geneticsandsociety.org/

<sup>&</sup>lt;sup>44</sup> On 4 March 1997 then U.S. President William J. Clinton issued a memorandum that stated: "Recent Accounts of advances in cloning technology, including the first successful cloning of an adult sheep, raised important questions. They potentially represent enormous scientific breakthroughs that could offer benefits in such areas as medicine and agriculture. But the new technology also raises profound ethical issues, particularly with respect to its possible use of clone humans." See Memorandum for the Heads of Executive Departments and Agencies, *Prohibition on Federal Funding for Cloning of Human Beings*, at http://grants.nih.gov/grants/policy/cloning\_directive.htm

himself Rael). It seems that the cloning claim is somehow bound up in the Raelian's religious beliefs that the soul of a person would live again if the person's DNA can be recreated. The goal of Raelian cloning appears to be eternal life for its members. Dr. Seed and the Railians are not the only people who want to clone human beings.

As mentioned in cloning technology before, technologies for human cloning may have two major proposed purposes. One has been reproductive cloning. The idea is that the cloned human embryo would be implanted into a womb and develops to be born. This purpose for human cloning is to help infertile couples to have child, or to reproduce a child who has died. The other purpose for human cloning has been therapeutic cloning. The idea is to clone an early embryo of a patient who has a degenerative disease, then use the embryo for production of embryonic stem cells, in hoping of treating the patient. The difference between the two reasons for human cloning is simply the purpose for which the embryo is used, that is, a born child or embryonic stem cell treatments.<sup>45</sup>

Human stem cell research open up promising medical possibilities to treat hitherto untreatable degenerative diseases by producing suitable replacement cells. For the long run, stem cell cloning technology, combination of genetic engineering, may make the xeno-

<sup>&</sup>lt;sup>45</sup> See DAVID A. PRENTICE, *supra*, note 39, at 22

transplantation technique practical and pragmatic.<sup>46</sup> At this early stage in the science, embryonic stem (ES) cells seem the most likely source of the widest range of cell types and thus of treatments. However, they are isolated by breaking open an embryo and removing the inner cells from the human blastocyst. This process will necessarily and inevitably destroy and terminate the human embryos, thus raising major ethical problems over the life status of those embryos.

For some, the early embryo is just a ball of cells with no formed human characteristics, justifying research for medical benefit. For others, all research on the embryo is unacceptable on principle because the embryo is as fully human in status as a baby. Adult stem (AS) cells may be alternatives as the more capable route for helping patients, but they could also pose serious ethical problems if hopes for fighting against fatal diseases are not realized.

Taken as a whole, no matter whether its goal is for reproduction or for research, no matter whether the source of stem cells is from an early embryo, a few months old fetus, or an adult body, the human cloning technology is without doubt one of the most complicated and controversial topics in our day, and has been the subject of intensive public debates ever since. Although most people seem to oppose the quick development of human cloning technology, there are still many people who are in favor of it and giving their great hope to its future welfare to the humanity.

<sup>&</sup>lt;sup>46</sup> The preface "*xeno*" means stranger or foreigner in Greek. The term "xenotransplantation" refers to the technique that transplants animal organs into humans.

# A. Important Justifications for Human Cloning Technology

There are many ways in which human cloning technology is expected to benefit humans. Most people who favor the cloning of humans believe that cloning should be allowed for some legitimate reasons. However, they also recognize that the technology is just in its early stage and most part of it does not currently exist. Therefore, when they speak for human cloning technology, they are not talking in terms of today or next month. Rather, they are talking about a future technology that has successfully gone through long-term developments and some inappropriate or dangerous procedures to the mother, the child, or the patient have subsequently been renovated. Below are the main reasons, but far from complete, why people speak in favor of the human cloning technology.

#### 1. Help Infertile Couples

One of the primary reasons put forward by those who favor human cloning technology is that it can help infertile couples that do not produce eggs or sperm have children genetically related to one of them. If a man could not produce sperm, he could still produce offspring by cloning. On the other hand, if a woman could not produce eggs, she could produce offspring by cloning as well. Thus, if male and female are not normatively complementary and generatively significant, babies need not come from male and female complementary. The clone is the ideal emblem: the ultimate "single-parent child."<sup>47</sup> Parents could conceivably clone more than one child and every child could be genetically related to each of the parents. Thus, there could be a family with a mix of the parents' genes. If this technology is no longer a dangerous procedure to the mother and child, it could be an outgrowth of current reproductive technologies to help infertile couples, such as *in vitro* fertilization (IVF).<sup>48</sup>

Current treatments for infertility, in terms of percentages, are not very successful. One estimate is that the successful rate for current infertility treatments including IVF are less than ten percent. It is so embarrassed that infertile couples that suffered physically and emotionally painful procedures are only seeking for a small chance of having children. More frustratingly, many couples run out of time and money but cannot make them successfully have any children at all. In respect of effectively forming an embryo, human cloning technology, which is considered as the last and best hope for having children, could make it possible for many more infertile couples to produce offspring than ever before.

### 2. Recreate A Lost Child or Relative

<sup>&</sup>lt;sup>47</sup> See Leon Kass, *The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans*, in THE HUMAN CLONING DEBATE 137 (Glenn McGee, Arthur Caplan eds., Berkeley Hills Books, 4<sup>th</sup> ed., 2004)

<sup>&</sup>lt;sup>48</sup> With *in vitro* fertilization (IVF), eggs from the mother and sperm from the father are mixed together in a laboratory and a resulting embryo is then implanted in the mother. The difference between that and cloning is that instead of an egg being mixed with a sperm, an egg minus its DNA, through nuclear transplantation or somatic cell nuclear transfer, is mixed with another cell to form an embryo. The embryo in both cases has to be implanted in the mother's womb for further development.

Loss of child may be the worst tragedy that can happen to a parent. After losing a child in a fire, car accident, or other unavoidable disaster, the grief-suffering parents often say that they would like to have their perfect baby back. Human cloning technology would allow a parent to recreate a dead child or relative to seek redress for his or her loss. When a child is dying, cells would be taken from the child so that the child could later be cloned. While the new child would not actually be the child who died, it would in some way help take the sting out of the death, by being a new child who looked very much like the deceased one, and had the same genetic makeup. It should be noted that human cloning technology would allow such parents to have a twin of their lost child, but it would be like other twins, a unique individual and not a carbon copy of the child that was lost.

In an imaginary scenario where a father, mother, and child were involved in a deadly car accident, the father is killed instantly, and the child is critically injured and dying. If the mother took cells from the dying child, and then cloned that child, it could allow her to preserve a connection with both her dead husband and her dying child. Under this circumstance, human cloning technology would allow the mother and the wife to create new life as a partial human answer to the grievous misfortune of her child's untimely death, and to continue the name and biological lineage of her deceased husband.<sup>49</sup>

## 3. Exercise Procreative Liberty

Procreative liberty, the freedom of a person to decide whether or not to have offspring, is generally thought to be an important instance of personal liberty. It is a deeply rooted ethical and legal value and pervades many of our social practices. People have a right to clone themselves, in the same way that they have a right to other reproductive-related technologies and procedures such as contraceptives and in vitro fertilization. Thus, if the motive of a parent to clone a child is so closely related to the interests, practices, and understanding that make procreation and having and rearing children a value activity, his or her right to clone embryos, other children, third parties, self, non-marriage mates, sexual partners, or his or her own parents should be respected and treated equivalently.<sup>50</sup> Once it is judged to be no less safe than natural reproduction, human cloning as a reproductive right should be allowed.

In this light, it would also give homosexuals the right to have children related to them. Human cloning technology may someday be made possible to allow two gay men to take twentythree chromosomes from each male and put them into a single egg to truly have a baby of their

<sup>&</sup>lt;sup>49</sup> See The President's Council on Bioethics, Human Cloning and Human dignity: An Ethical Inquiry 79-80 (U.S. Government Printing Office, July 2002)

<sup>&</sup>lt;sup>50</sup> See John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX L. REV. 1371 (1998)

own. Also two lesbian women could use this technology to conceive a child of their own using their individual twenty-three chromosomes. Based on current knowledge of reproductive cloning technology, it is practicable that in a lesbian couple, one woman could be cloned and then the embryo brought to term in either of the women. On the other hand in a gay couple, one man could be cloned, but they would have to find a woman to donate an egg and a surrogate mother to contribute a womb to bring the cloned embryo to term.

## 4. Have Offspring Free of Genetic Defects

Based on current knowledge of bioengineering in life science, human cloning technology may help couples or parents ensure that they would have their offspring free of defective genetic material that would cause deadly diseases or other disorder syndromes. For example, if both parents had a recessive gene for a deadly genetic disease. Since each parent has only one gene for the disease, each parent is free of that disease. Although the genetic disease only shows up if a child has two genes for it, one from each parent, there would still be a one-in-four chance that a child of theirs would inherit that deadly disease. If a parent decides to reproduce his or her offspring through human cloning technology, the resulting child will not have the genetic disease, because he or she will have the same genetic makeup of the parent who has only one gene for the disease.<sup>51</sup>

<sup>&</sup>lt;sup>51</sup> See JAY D. GRALLA & PRESTON GRALLA, *supra*, note 40, at 147

#### 5. Provide Medical Cures

Imaging that a child had an incurable disease and the only way to cure him in later life would be with a transplant of some kind – a kidney or a bone marrow transplant. Also imagine that no donor with a match for the organ can be found, and so the chances that the child would reject any transplant would be high. Without a transplant, the child will die. If the child could be cloned under reproductive purpose, then in a few years, the resulting clone could donate an organ or bone marrow. The older child would be saved, and the resulting younger cloned child would live as well, because bone marrow regenerates, and people can live with only one kidney. In that way, parents would have two healthy children, but without cloning, their only child would have died. So they would have a new life – the new child – and save an existing life.

In addition, human cloning technology could also use nuclear transplantation technique to produce human stem cells under therapeutic purpose. Based on the same scenario as above, instead of having a new cloned child, stem cells from the umbilical cord of the child may be cultured in petri dishes and develop into tissues such as kidney or bone marrow on demand. New tissues may be transplanted into the child's body. Since the DNA of new kidney or bone marrow is matched for the child, they will be less likely to be rejected as foreign matter by the immunity system in the child's body.

#### 6. Take A Step towards Immortality

Those who protect human cloning technology have taken to calling human clones "laterborn twins" of the person whose genetic material was cloned. The idea is that since the cloned being has the same genetic material as the original, they are twins. And it is a "later-born twin" because it is born decades after the person whose genetic material is being cloned. As a result, human cloning essentially means taking a human being's DNA and reversing its age back to zero. Dr. Richard Seed has commented that human cloning will help us understand how to reverse DNA back to age twenty or whatever age we want to be. This technology would be a step towards a fountain of youth.

Furthermore, some people feel that they would have an immortality of a kind in having this "later-born twin" because their DNA would live on, even when they die. And there are those who want to have a "later-born twin" because they believe that twins have a special relationship that other people do not have, and they want to have that same sense of closeness that twins have. In this way of thinking, an especially strong bond would be formed because the resulting child would be both a child and a "later-born twin" to the parent.<sup>52</sup>

# **B.** Critical Controversies over Human Cloning Technology

<sup>&</sup>lt;sup>52</sup> See Simon Smith, *The Benefits of Human Cloning*, in THE HUMAN CLONING FOUNDATION (1998), also available at http://www.humancloning.org/benefits.php

Despite the claims of some research groups and scientists that they have already cloned a human being, human cloning is not possible today. But since science always has a way of making today's impossibility into tomorrow's reality, the human cloning debate still rages on. One of the most powerful arguments against human cloning technology is how it would harm the child who will be born as a result of its reproductive procedure, not only medically but also in a variety of other ways. Below are the critical arguments, but far from complete, why people want to totally or partially ban the human cloning technology.

### 1. Disrespect for the Dignity of the Cloned Child

One of the most difficult and the most satisfying things about being human is developing a sense of self – understanding our particular capabilities, wants, needs, strengths, and understanding how we fit into the world. A vital part of this is learning from and breaking away from our parents and in understanding how we are similar to and different from our parents. If the human cloning technology could successfully reproduce a child, it would diminish the individuality or uniqueness of the cloned child. No matter whether the cloned child were cloned from the cells of parents or others, it will be difficult for the cloned child to build his or her sense of self. Furthermore, it could lead to a devaluation of clones in comparison with non-clone.

In addition to the obvious physical risks to the cloned child, the reproductive cloning would infringe on the freedom, autonomy, and self-determination of the child, as a result, against the deeply rooted values and concerns on human individuality and freedom under current human rights jurisprudence. Consequently, it may totally destroy the child's dignity as a human and violate his or her own right to an open future. The cloned children would unavoidably be raised in the shadow of their nuclear donor, in a way that would strongly tend to constrain individual psychological and social development. This is a cruel, inhuman and degrading treatment to the child. Thus, to what extent human cloning would undermine individuality or uniqueness is what should be thoroughly investigated before the human cloning technology has been fully realized?<sup>53</sup>

#### 2. Demolish Familial Relationships

Familial relationships help define who we are as individuals, and to a great extent are the bedrock upon which society is based. Human cloning is a form of asexual reproduction technique. A child produced by reproductive cloning technology would be the genetic duplicate of an existing person. Therefore, the consequence of this cloning procedure would confuse the cloned child's kinship with his or her family members, and thus cloud and destroy any sense of familial relationships in any kind. Since the nature of familial relationships between the cloned

<sup>&</sup>lt;sup>53</sup> See Dan W. Brock, Human Cloning and Our Sense of Self, 296 SCIENCE 314-16 (2002)

child and the social parents and others would be a crucial part of the physical well being of the cloned child, it should be cautiously considered here.<sup>54</sup>

For example, a cloned boy would be a twin brother to his father because he would have the same genetic material as his father. He would also be his mother's brother-in-law because he would be a brother to his father. If he had any children, he would even be their great uncle because they are his father's grandchildren. His family relationship would become more confusing if his mother also had a cloned child. Thus, the resulting child would be neither a son nor a twin brother of the person being duplicated. There may not even be words to describe the family relationship in this situation. They would become a new category of human being: the clone. As a result, the familial relationships preserved in the core of our traditional human society would be totally demolished.

### 3. Consider the Cloned Child Commodities

Producing a child by human cloning technology turns that cloned child into a commodity or merchandise, in return for certain compensation or a fair market price, provided that an offspring is offered with a specific or selected genetic makeup. Even more, the cloned child as a commodity or a merchandise manufactured through some patented reproductive technology and procedure could be sold to the highest bidder at an embryo market.

<sup>&</sup>lt;sup>54</sup> See Helen Watt, *Thinking Twice: Cloning and in Vitro Fertilization*, 18 ETHIC & MEDICINE 35-43 (2002)

Consequently, human cloning technology would foster an understanding of children and of people in general, as objects that can be designed and manufactured to possess some specific characteristics. It is no different than buying any other commodity or merchandise in an ordinary market. Expecting a big payoff from the child, the parent would be willing to pay top dollar for the cloned embryo of an outstanding figure such as a Nobel Prize winner or a well-know athlete, while the one without prestigious genetic background would be less expensive, free of charge, or even totally unseen. Either way, the human dignity of the cloned child would be totally disregarded.<sup>55</sup>

# 4. Cause Medical Dangers

Human cloning has a variety of medical dangers to the cloned child. According to experience gained from animal cloning experiments, cloned mammals die younger than noncloned mammals and suffer prematurely from disease of old age, such as arthritis. Dolly the Sheep is a notable example. In addition, cloned animals are at a higher risk of having genetic defects and of being born diseased and deformed. Studies have shown that the cloned mice have died prematurely from tumors, damaged livers, and pneumonia.

Since the human cloning technology has not yet been tested with human subjects, and scientists cannot rule out the possibility of mutation or other biological damage, the National

<sup>&</sup>lt;sup>55</sup> See B. Gogarty, What Exactly Is An Exact Copy? And Why It Matters When Trying To Ban Human Reproductive Cloning in Australia, 29 JOURNAL OF MEDICAL ETHICS 84-89 (2003)

Bioethics Advisory Commission (NBAC) report concluded that "[A]t this time, it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning [which would] pose unacceptable risks to the fetus and/or potential child."<sup>56</sup>

The Whitehead Institute for Biomedical Research in Cambridge, Massachusetts studied ten thousand genes in the livers and placentas of cloned mice and found that hundreds of the genes had abnormal activity patterns. Even clones that appear normal have subtle differences in their genetic makeup when compared to the animal from which they were cloned. Thus, the attempt to clone humans may also be dangerous and irresponsible to the cloned child who has no opportunity or means to decide whether to give consent to this experimentation with his or her own will or informed knowledge.<sup>57</sup>

In a human cloning procedure, it is not only the child who will be facing medical dangers, the mother will as well. There is evidence that human reproductive cloning could be dangerous for the mother and the child. Dr. Leon Kass, the chairman of the President's Council on Bioethics, warns that animal's studies "[S]uggest that late-term fetal losses and spontaneous abortions occur substantially more often with cloned fetuses than in natural pregnancies. In

<sup>&</sup>lt;sup>56</sup> See National Bioethics Advisory Commission, *Cloning Human Being*, in REPORT AND RECOMMENDATIONS OF NATIONAL BIOETHICS ADVISORY COMMISSION (9 June 1997) Also note that the NBAC was dissolved in October 2000.

<sup>&</sup>lt;sup>57</sup> Regarding Information against human cloning, see generally at http://www.cloninginformation.org/

humans, such late-term fetal losses may lead to substantially increase maternal morbidity and mortality." <sup>58</sup>

The National Academy of Sciences also concludes that "[R]esults of animals studies suggest that reproductive cloning of humans would similarly pose a high risk to the health of both fetus or infant and lead to associated psychological risks for the mother as a consequence of late spontaneous abortions or the birth of a stillborn child or a child with severe health problems." Based on evidence that cloning may be even more dangerous in humans than in other mammals, Dr. Ian Wilmut told the BBC that "[T]he most likely outcome of any attempt to do that [clone a human] would include late abortions, birth of children who would die, and worse of all, the birth of children who would survive but would be abnormal."

In respect of therapeutic or experimental stem cell cloning, those who oppose the procedure insist that human life starts right after a human cell becomes a fetal embryo and is capable of dividing. The research cloning technology may still contradict fundamental principles of medical ethics, that no human life should be exploited or extinguished for the benefit of another. Therefore, any form of human cloning ought to be banned, and anything other than a total ban on human cloning would be unethical.<sup>59</sup>

<sup>&</sup>lt;sup>58</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra*, note 49, at 90

<sup>&</sup>lt;sup>59</sup> See, e.g., President George W. Bush Calls on Senate to Back Human Cloning Ban, Remarks by the President on Human Cloning Legislation, available at http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html

## 5. Cause Societal Dangers

It is not merely individuals who would be harmed by human cloning technology, society as a whole would be harmed as well to such that degree that it would not be the kind of culture that many people would want to love. In fact, the President's Council on Bioethics warned that "[T]he impact of human cloning on society at large may be the least appreciated, but among the most important, factors to consider in contemplating the morality of this activity."<sup>60</sup>

For example, human cloning technology could well lead to a new, even more effective form of eugenics.<sup>61</sup> In countries run by dictatorships, the government could sponsor a mass cloning campaign and clone people who it deemed had the proper genetic makeup. Furthermore, even in democratic societies in which the government might not be involved in cloning, human cloning technology could still lead to a kind of free market eugenics, particularly when it is combined with bioengineering techniques. Under this circumstance, an adult may have always wished that he could have been born with blue eyes instead of brown eyes, and blonde hair instead of brown hair. He could clone himself and bioengineer his clone to have blue eyes and blonde hair through manipulating the genes to be placed into the cloned embryo.

<sup>&</sup>lt;sup>60</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra*, note 49, at 112

<sup>&</sup>lt;sup>61</sup> "Eugenics" is a pseudoscience with an attempt to breed a better human race by encouraging those with good genes to have children, but discouraging those with bad genes from having children.

As a result, society would not be populated by the diverse, energizing mix of people and their different features and unique talents that we have today, but instead increasingly by a homogenized ideal human. On a mass scale, this could lead to a kind of master race being created, one based on fashion, perhaps, or on what attributes people think will lead to a cloned offspring's financial benefits. The ideal human could be the subject defined by advertising executives. Biotech companies would sell the best or most desirable genetic material to those who want to be cloned, and so flood the media with advertising to convince people that their cloning procedures and super-value genes are the ideal ones.<sup>62</sup>

# C. Public Concerns about Human Cloning Technology

Public concerns regarding human cloning include emotional, philosophical, religious, and other issues, which will be discussed later. Basically, there are few themes involved in crucial concerns of the public.

### 1. Safety of the Technology

In the event that human embryos are successfully cloned and implanted into a woman's uterus, the question of what percentage of these embryos is likely to be born healthy arises. There are numerous reasons why cloning might present a significantly higher risk of birth defects

<sup>&</sup>lt;sup>62</sup> See JAY D. GRALLA & PRESTON GRALLA, UNDERSTANDING CLONING 161-162 (Alpha Books, 2004)

or even of problems that would only manifest later in the life of the cloned individual, as compared to the risks present in natural reproduction. No matter what the source of risk, it would be unacceptable to most people to allow human cloning without exhaustive evaluation of its impact on embryo development.

However, the safe and gradual scientific development of human cloning technologies may be possible. By carefully and simultaneously characterizing large numbers of preimplantation cloned embryos for gene expression levels and for morphological development, scientists might develop reliable molecular markers (or other predictors) of an embryo's potential to develop and grow normally. The status of these predictors would be assessed every time an embryo is cloned, and only potentially healthy embryos would be considered for implantation. Researchers in human reproductive biology have already successfully undertaken this approach. Scientists at Cornell University Medical College have found that the expression of genes from the insulin-like growth factor family correlates well with the morphological growth potential of donated day-three human embryos.<sup>63</sup>

In addition, scientific research on human and animal somatic cell nuclear transfer is necessary to improve the safety of human cloning. If society decides to go forward with the

<sup>&</sup>lt;sup>63</sup> See H.C. Liu, Z.Y. He, C.A. Mele, L.L. Veeck, O.K. Davis, & Z. Rosenwaks, *Expression of IGF's and Their Receptors Is A Potential Marker for Embryo Quality*, 38.4 AM. J. REPRODUCTIVE. IMMUNOLOGY 237-245 (1997)

development of human cloning technology, safety issues must be resolved to the full satisfaction of the public and scientists before any uterine implantation of human embryos is allowed.

#### 2. Uncertainty of Science

A number of scientific uncertainties remain regarding somatic cell transfer as a cloning technique, and its feasibility in human beings. It is unclear whether the methods employed for sheep and cows might be directly transferable to humans. An example of scientific uncertainty arises from the fact that the contributions of the male and the female genomes to a zygote's development differ. Sex-specificity of developmental phenomenon (an example is genomic imprinting, which "brand" genomes according to their parental origin, male or female) would be eliminated in a clone whose genome is derived from a single parent. The phenomenon of genetic imprinting may also affect the ability of nuclei from later stages to reprogram cellular development. The consequences of having a uniparental genome are currently unknown. The extent to which cellular aging will affect the ability of somatic cell nuclei to program normal development once the cell has been reprogrammed to act like a young cell is also unknown.

It was evident that mutations that have accumulated over time in somatic cells could affect nuclear transfer efficiency and lead to cancer or other diseases in offspring. Human disease resulting from uniparental disomy has been increasingly recognized, e.g., Angelman syndrome and occasional cases of recessively inherited disease, such as cystic fibrosis, when only one parent is a documented carrier of the disease allele. Whether a clone would be at a higher risk of accumulating such deleterious mutations is not known, either. These unresolved scientific issues continue to prompt questions about the safety of cloning by somatic cell nuclear transfer.<sup>64</sup>

### 3. Imperative of Morality

Among other religions, the Abrahamic faiths which include Judaism, Christianity, and Islam attach a unique and continuing moral and spiritual significance to the individual persons. Since the world is God's creation, all the elements that make it up have an appropriate value and attain a corresponding ethical status. Most religious believers may accept the carefully controlled use of animals by human beings for food and scientific and medical experiments undertaken for serious and beneficial ends. However, the status bestowed on each human creature by God the Creator renders an immediate ethical consequence of theological understanding that no human being is available for instrumental use of any kind. Beyond the community of those who share the religious insight mentioned above, there is also a wide acceptance of the same moral stance.

Even though human clones have always existed and brought about by the natural process of the birth of identical twins, the way in which that happens is, of course, entirely different from

<sup>&</sup>lt;sup>64</sup> See The Council On Scientific Affairs, *Cloning and Embryo Research*, in REPORT OF THE COUNCIL ON SCIENTIFIC AFFAIRS 7 (June 1999), also available at http://www.ama-assn.org/

the way used to produce Dolly the sheep and other cloned animals. An attempt to use a similar procedure to produce a cloned human being will undoubtedly also require a large number of trails before success is achieved and will involve similar uncertainties about long-term consequences. In contrast to the work that led to the birth of the first IVF baby, the procedures would be the result of radical human manipulation and not simply the facilitating of a natural process.

Likewise, the dream of scientists and many patients of applying human embryonic stem (ES) cells technology to treat the seriously ill have been interrupted by the anxious tone of voice of those who see human embryos as vulnerable living humans. Theses objectors may not reject stem cell research in itself; for they recognize that it may offer new forms of treatment and insights into human development. Instead, they reject human embryonic stem cell research because it necessarily involves the destruction of early human embryos. Those objectors insist that early embryos have the same moral significance as living human beings and ought to be owed the same protections. Therefore, to destroy human embryos is just as to destroy individual living human beings and is apparently wrongful.<sup>65</sup>

<sup>&</sup>lt;sup>65</sup> See Cynthia B. Cohen, Renewing The Stuff Of Life – Stem Cells, Ethics, And Public Policy 59 (Oxford Press, 2007)

# V. Conclusion

The successful use of somatic cell nuclear transfer technology as a method for cloning mammalian farm animals such as sheep, cows and mice, has brought current society one-step closer to the possibility of cloning human beings via nuclear transplantation. Human cloning may present a number of challenges to current society. The questions of whether they are ethical, social, legal, philosophical, dogmatic or emotional ones will of course draw current society much attention.

On the other hand, the human cloning technology may also offers tremendous potential benefits, such as cloning for medical purpose to cure diseases suffered by many people. Thus, it is important to carefully address and prudentially consider each of the reasonable and expectable questions raised. This includes a profound consideration of whether any proposed argument outweighs potential benefits and warrants unconditional prohibition of human cloning and its related technologies. Simply banning or restricting advanced experimentation or pragmatic practice of human cloning technology without profound considerations may not be the best interest for the whole human being.
# <u>Chapter 2</u>

# <u>Ethical and Religious Concerns on Human Cloning</u> <u>Technology</u>

# I. Introduction

The cloning technology is an extension of stem cell research that had been ongoing for at least fifty years using nuclei derived from non-human embryonic and fetal cells. The demonstration that nuclei from cells derived from an adult animal could be reprogrammed and the full genetic complement of such a cell could be reactivated well into the chronological life of the cell sets the idea that human beings might someday be cloned through a single somatic cell without any kind of sexual reproduction process.

The issues surrounding the cloning technology of human beings have long been the subject of considerable public attention and sharp moral debate among philosophers, scientists, ethicists, and others around the world. This provided opportunities for initiating a thoughtful analysis of many dimensions of ethical and legal issues that touched fundamental aspects of humanity, including a careful consideration of the potential risks and benefits of this novel technology. Although a cloned human child has yet to be born and the animal experiments have had low rates of success, the recent production of functioning mammalian cloned offspring suggests that the eventual cloning of humans must be considered a serious possibility.

This chapter will examine important ethical and religious concerns under moral aspects in contemporary techniques of cloning procedure substantially relating to humans. In general, morality is the attempt of individuals, or of groups, to live out in daily attitudes and actions their vision of the highest good. Moral systems are normally tied to religious traditions. In contrast, ethics employs a common or public language in justifying assertions about prescribed or proscribed attitudes and actions. Moral systems tend to see things in terms of right and wrong, black and white, whereas ethic systems are more at home than morality with uncertainty and ambiguity.<sup>66</sup> The intense attention among ethical, religious, and moral perspectives will give to the human cloning technology in both its potential uses for reproduction as well as for medical research.

Consequently, this will raise issues about identity and individuality of the cloned person and his or her processor, the meaning of having children, the difference between procreation and

<sup>&</sup>lt;sup>66</sup> See Ernle W. D. Young, *Ethical Issues: A Secular Perspective*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, SCIENCE, ETHICS, AND PUBLIC POLICY 163-164 (Suzanne Holland, Karen Lebacqz, & Laurie Zoloth eds., Massachusetts Institute of Technology Press, 2001)

manufacture, the distinction between the eugenics to a race and the well-being for a child, and the unnatural relationship between generations. It also initiates new questions about the beginning of human life, the moral status of the human blastocyst or embryo, the manipulation of some human beings for the benefit of others, the freedom and value of biomedical inquiry, our obligation to heal the sickness, and the respect and protection owed to nascent human life.<sup>67</sup> Different aspects and situations about human cloning technology among nations or regions in the international community will also be reviewed at this stage.

# II. Ethical Concerns

# A. Playing God the Creator

The ethical issues relating to the topic of cloning technology mainly focus on human cloning. There have been a number of controversies over the years surrounding those who want to clone humans or those who have claimed to clone humans. In 1998 Dr. Richard Seed announced that he planned to set up human cloning clinics in 10 to 20 locations in the United States and 5 to 6 internationally to help infertile couples have children who would be genetically

<sup>&</sup>lt;sup>67</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, EXECUTIVE SUMMARY, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (U.S. Government Printing Office, July 2002)

related to one of them or to replace a family member who died or was killed. He pointed out that the very act of researching human cloning would result in other medical breakthroughs that would help humankind as a whole. However, the mystics surrounding Dr. Seed tends to raise the argument that human cloning oversteps certain moral and ethical boundaries and may be to "playing God the Creator."<sup>68</sup>

It is common that whenever a scientific progress offers the opportunity for some novel kind of human intervention in the order of nature, there will be voices raised to oppose the procedure on the grounds that it is inappropriate for human beings to exercise powers that should be reserved for God the Creator alone. Objections to the act of originating a child by human cloning based on the appropriateness of the act are of two kinds: those that hold that the act is intrinsically wrong and those that claim that the act is wrong because of its potential awful consequences. Of the former, the typical objection which may be classified as utilitarianism appeals to God the Creator's will or to the naturalness of human, sexual reproduction. On the other hand, of the latter, the objection which may be classified as consequentialism appeals to awful consequences from human cloning to human society, to the family, or to the child originated by cloning technology.<sup>69</sup>

<sup>&</sup>lt;sup>68</sup> See The California Advisory Committee On Human Cloning, *Cloning Californians?* In REPORT OF THE CALIFORNIA ADVISORY COMMITTEE ON HUMAN CLONING 31 (2002)

<sup>&</sup>lt;sup>69</sup> See GREGORY E. PENCE, FLESH OF MY FLESH, THE ETHICS OF CLONING HUMANS xii-xiii (Rowman & Littlefield Publishers, Inc., 1998)

# 1. Utilitarian Objections

Utilitarian objections insist that cloning violates God the Creator's will and contradicts God the Creator's choice by creating a fetus or an infant in a way that does not depend on human sexual gathering or make possible the divine inculcation of a soul. That may be true, but some critics assert that so does *in vitro* fertilization. An egg and a sperm are united outside the human body in a glass container. The fertilized egg is then put into the body of either the woman who produced it or another woman hired to bear the infant. When first proposed, *in vitro* fertilization was ethically suspect. Today, it is in turn generally accepted for good reason by the public. The scientific progress provides one or both human bodies that lack a reasonable chance to produce an infant. Cloning removes one of the conjugal partners, but it is hard to imagine that God the Creator's desire to bestow a unique soul can be blocked by the fact that the infant does not result from an egg and sperm's joining but instead arises from an embryonic egg's reproducing itself.<sup>70</sup>

#### 2. Consequentialist Objections

Consequentialist objections concern the well-being and dignity of the cloned child bestowed by God the Creator. Their most weighty moral objections to clone human are of two types: those concerning the safety of the cloning process and the physical and genetic harms to the child, and those concerning possible psychological harm to the child, such as diminished

<sup>&</sup>lt;sup>70</sup> See LEON R. KASS, JAMES Q. WILSON, THE ETHICS OF HUMAN CLONING 63-64 (The AEI Press, 1998)

sense of individuality and personal autonomy from either unrealistic parental expectations or a confused identity. Even if the safety objection is overcome one day, all the moral weight of objections to human cloning will still rest on the psychological factors mentioned above. It can be expected that there are ethical concerns about a degradation of the quality of parenting and family life if parents are tempted to seek excessive control over their children's characteristics, to value children according to how well they meet overly detailed parental expectations, and to undermine the acceptance and openness that typify loving families.

# **B.** Instrumentation of Human Person

In Dr. Richard Seed's view, helping infertile couples have children who are genetically related to one of them is the primary reason for human cloning. In fact, through *in vitro* fertilization (IVF) technologies, it is possible to allow an egg, minus its DNA to be combined with another cell to clone an embryo, which is implanted into the mother's uterus. If a couple may have their child through an *in vitro* fertilization facility, the human cloning technology may of course be one of their other available alternatives.

# 1. Instrumental Use by Other Human

In view of the scientific progress in the field of animal cloning, most people may accept the proper use of livestock for food supplies, toil powers, and other human needs. They may also

agree to the carefully controlled use of animals in scientific and medical experiments undertaken for serious and beneficial purposes. There may be, therefore, an ethically acceptable degree of instrumental use of animals by human beings, just as under Charles Darwin's theory "On the Origin of Species by Means of Natural Selection", or "the Preservation of Favoured Races in the Struggle for Life," in the created order through purely natural forces there may be an instrumental use of living beings by other living beings in the food chain that sustains life on earth. The experimental work that led to the birth of Dolly seems to find an acceptable place within this general understanding. There was a high wastage rate (two hundred and seventyseven attempts resulted in only one success) to expect a new animal cloning technique. As long as the purposes for which the research undertaken are certainly serious and significant, it does not seem that an important ethical issue arises to the extent that animal cloning is concerned. However, human cloning is a different matter.<sup>71</sup> Most people will not expect that it can easily find way out from the dilemma of the ethical maze.

Based on the fundamental freedom of reproduction under human rights jurisprudence, people should have a right through human cloning technology to clone themselves to reproduce their own heirs and offspring. Furthermore, human cloning could also provide a parent with an opportunity to recreate a dead child or relative to take the sting out of the loss, since the cloned

<sup>&</sup>lt;sup>71</sup> See John Polkinghorne, *Cloning And the Moral Imperative*, in HUMAN CLONING RELIGIOUS RESPONSES 36 (Ronald Cole-Turner ed., Westminster John Knox Press 1<sup>st</sup> ed., 1997)

person would look very much like the deceased one and have the same genetic makeup. In addition, today's communities have generally accepted the claim that homosexuals should have the reproductive right to have children genetically related to them. Again, the cloning-to-produce-children technology is with no doubt capable of satisfying such special needs.<sup>72</sup>

However, it should be noted that human cloning used for producing a child would procreate a person for reasons wholly detached from that person in his or her own self. As a clone for restoring a lost child or relative, the burden of being that person would be a deeply psychologically damaging imposition on the cloned person thus brought into existence. Based on generally-known theological philosophy, in the plan of God, anyone is a unique existence and no one should be a substitute for anyone else; each equally possesses value simply by being him or her own self and no other. The genetic uniqueness is an important source of our sense of who we are and how we regard ourselves. It is an emblem of independence and individuality. It endows us with a sense of life as a never-existed possibility.

#### 2. Human Created As A Means

It is disappointed that cloned children may experience concerns about their distinctive identity not only because each will be genetically essentially identical to another human being, but also because they may resemble in appearance younger versions of the person who is their

<sup>&</sup>lt;sup>72</sup> Regarding Pro-cloning information, see the Human Cloning Foundation, at http://www.humancloning.org/

"father" or "mother." This might constrain the clone's sense of self. Everything about the predecessor will appear before the expectant eyes of the cloned person. The value of the clone's life is thus nude and worthless. Furthermore, for an instrumental purpose to bring a person into being with the intention of producing as close a genetic match as possible for someone who needed a spare part or organ, such as kidney, bone marrow, etc., is of course ethically unacceptable. For the religious believer, human beings are the creatures made in the image of God. Thus, they should always be the end and never be the means. The instrumental cloning of human beings would no doubt be the most serious concern under traditional moral maxims in our society.

Although the ethics of human reproductive cloning may incur serious debates, especially regarding a cloned person created free from mortality or genetic disease, the medical and other professional communities unanimously affirm the importance of therapeutic or experimental stem cell cloning. Stem cells could potentially be transplanted into brain and nerve tissue to help cure disease and conditions such as strokes, spinal cord injuries, and degenerative brain and nerve conditions such as Parkinson's disease. They could also possibly treat diabetes, replace skin, clone organs, cure muscular dystrophy, and treat many other diseases. Those who favor therapeutic or experimental stem cell cloning do so for an obvious reason: It can lead to dramatic breakthroughs in science and medicine, saving countless lives as well as improving the quality of

countless lives. Since a fully developed human or animal embryo resulting from therapeutic or experimental human stem cell cloning has yet been found, the ethics of such technology and procedure may be hypothetical and less controversial at this situation.

# C. Disrespect for Human Life

All human lives on earth should be equally respected, yet either secular or religious thoughts have not readily agreed about the question of at what stage of fetal development the human person can be recognized as being fully present. Scientists may soon be able to extract stem cells from an early embryo and grow those cells to study and cure degenerative diseases. Critics object that extracting the stem cells destroys the embryo. They insist that if a life is a gift and bestowed by God the Creator, and the life starts at the time the embryo is successfully produced, each human embryo is the tiniest of human beings, any kind of research that destroys the stem cell possessing a nascent human life must therefore be objected. This notion suggests that stem cell research is driven by a crass utilitarian ethic that sacrifices the dignity of individuals by turning them into a means toward an end.<sup>73</sup> Whereas defenses for embryonic stem cell research argue that the freedom of research and right to be cured are also fundamental

<sup>&</sup>lt;sup>73</sup> See Ted Peters, *Embryonic Stem Cells and the Theology of Dignity*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, SCIENCE, ETHICS, AND PUBLIC POLICY 128-130 (Suzanne Holland, Karen Lebacqz, & Laurie Zoloth eds., Massachusetts Institute of Technology Press, 2001)

essences for advancing human life, there must be a balancing weight of interests between the life of human embryo and the life of fully human being.

#### 1. When Is Matter?

To date, for example, the United States has no federal law that prohibits cloning a child or bans either human or animal cloning for any other experimental purposes. This is not because most people favor cloning as a novel bioengineering technology to produce a child or enrich the human life. To the contrary, public opinion and almost all elected officials oppose it. In 2006, former President George W. Bush exercised his first veto to the bill which involved the more mysterious subject of stem cell research. Hoping to promote cures for diabetes, Parkinson's, and other degenerative diseases, Congress had voted to fund new embryonic stem cell research, in which scientists isolate cells capable of becoming any tissue in the body. The President refused to go along. He argued that the research is unethical because deriving these cells destroyed the blastocyst, an un-implanted embryo at the sixth to eighth day of development. The federal government, he declared, should not support the taking of innocent human life.<sup>74</sup>

In its Report to the British Government, the Warnock Committee proposed that, at the very least, the human embryo was entitled to a profound ethical respect by virtue of its

<sup>&</sup>lt;sup>74</sup> See E.G., George W. Bush, *President Discusses Stem Cell Research Policy*, Office of the Press Secretary, the White House, 10 July 2006, available at http://www.whitehouse.gov/news/releases/2006/07/20060719-3.html; Message to the House of Representatives, Office of the Press Secretary, the White House, 19 July 2006, available at http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html

possessing the potentiality for full human development. On this basis, the Committee made the recommendation to the House of Commons that no experimental procedure should be permitted to be carried out on an embryo beyond the age of fourteen days from fertilization, as after that time cell differentiation begins to appear with the primitive streak which is one of the first signs of gastrulation.<sup>75</sup> The recommendation has incorporated into the Statute Law of the United Kingdom. It is a clear implication of the Warnock Committee's deliberations that the experimental creation of human beings is morally unacceptable.<sup>76</sup>

On September 7, 2001 a report was published in *Beijing Youth Daily*: Professor Chen Xigu in the Experimental Animal Center of Sun Yat-Sen University, transferred a skin cell nucleus from a seven year old boy into a rabbit's denucleated egg, and created an embryo. The aim is to use cloning to develop cures for such illnesses as diabetes and Parkinson's disease. Chen said that he had been able to grow the hybrid embryos only to the stage at which they remain a cluster of undifferentiated cells. He acknowledges that he was far from his goal of extracting stem cells from the embryos and turning them into treatments.

After a series of profound discussions among Chinese scientists, Benfu Li, the director of the Chinese Society of Medical Ethics, outlined the consensus of ethical principles on embryo

<sup>&</sup>lt;sup>75</sup> The primitive streak is a structure that forms during the early stages of avian, reptilian, and mammalian.

<sup>&</sup>lt;sup>76</sup> See House of Commons Select Committee on Science and Technology, *The Cloning of Animals from Adult Cells*, REPORT OF HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY (Her Majesty's Stationery Office, 1997)

stem cell research. He thought the embryo stem cell research should obey the principle of respect since the embryo of a certain value is a human biological life, which should be respected. It cannot be controlled or damaged at will without enough reason. Human embryonic stem cell research has potential value in treating human various diseases, so stem cell research using embryos should be permitted and supported.<sup>77</sup> Most Chinese scientists support the research using embryos up to fourteen days old, because there are less harms if destroyed embryos are less than fourteen days old than the harm from a patient dying without curing. A 14-day-old embryo is simply a cluster of cells without bones, organs or other traits. But the questions about whether the stem cell research using hybrid embryos in any condition should be objected are still unsettled.<sup>78</sup> However, Chinese government officials have not announced their officially support of research using cloned human embryo.

#### 2. Moral Value of the Human Embryo

The debates over stem cell research concern at least three policy issues. First, should embryonic stem (ES) cell research be permitted? Second, should it be funded by the government? Third, should it matter, for either permissibility of funding, whether the stem cells are taken from already existing embryos left over from fertility treatments or from cloned

 <sup>&</sup>lt;sup>77</sup> See Benfu Li, *The Principles of Embryo Stem cell research*, 10 CHINESE MEDICAL ETHICS, 21-23 (October 2001)
<sup>78</sup> See Xiangxing Qiu, *Studies on Human stem Cells and some Related Ethical Issues*, 22 MEDICAL AND PHILOSOPHY 54-58 (October 2001)

embryos created for research? The first question is the most fundamental and most intractable. The main objection to embryonic stem cell research is that destroying a human embryo, even in its earliest stages of development, and even for the sake of righteous ends, is morally abhorrent; it is like killing a child to save other people's lives.<sup>79</sup> Nevertheless, it may be acceptable by the international community that the validity of this objection will depend on the moral status of the embryo. It is acknowledgeable that, for strong moral reasons, any bioengineering progress must come by means that do not involve the production, use, and destruction of cloned embryos and that do not reduce nascent human life to resource for our exploitation.

# **D.** Experimentation on Human Beings

The only way to test the efficacy of the kind of technique used to cloned Dolly is to implant the resulting embryo and see if its gestation proceeds to term and results in a viable birth. In the case of sheep, two hundred and seventy-seven attempts were necessary before success was achieved. There are still unresolved questions about how long such a cloned will live and how healthy it will prove to be. Likewise, an attempt to use a similar procedure to produce a cloned human person would undoubtedly also requiring a large number of trials before success was achieved and would involved similar uncertainties about long-term consequences.

<sup>&</sup>lt;sup>79</sup> See MICHAEL J. SANDEL, THE CASE AGAINST PERFECTION, ETHIC IN THE AGE OF GENETIC ENGINEERING 102-104 (The Belknap Press of Harvard University Press, 2007)

In contrast to the work that led to the birth of the first *in vitro* fertilization baby, the procedures that related to human cloning technique would be the result of radical human manipulation and not simply the facilitating of a natural process. As happened in animal cloning procedure, it would inevitably require the production of experimental human beings. This is apparently morally unacceptable. Since the World War II, various codes for the ethical conduct of human experimentation have been adopted around the world, such as the Nuremberg Code of 1947 and the Helsinki Declaration of 1964.<sup>80</sup> These codes and regulations were formulated in direct response to serious ethical lapses and violations committed by research scientists against the rights and dignity of individual human beings.

#### 1. Human As A Research Subject

The Nuremberg Code laid out ten principles for the ethical conduct of experiments, focusing especially on voluntary consent of research subjects, the principle that experiments should be conducted only with the aim of providing a concrete good for society that is unprocurable by other methods, and with the avoidance of physical or mental harm. The Helsinki Declaration stated, among other things, that research should be undertake only when the prospective benefit clearly outweighs the expected risk, when the research subject has been fully

<sup>&</sup>lt;sup>80</sup> See NUREMBERG REPORT, TRIAL OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW, n10, v2, pp. 181-182 (U.S. Government Printing Office, 1949); also see HELSINKI DECLARATION, 18<sup>TH</sup> WORLD MEDICAL ASSOCIATION GENERAL ASSEMBLY, Ethical Principles for Medical Research Involving Human Subjects, adopted in Helsinki, Finland, June 1964, and amended in OCTOBER 1975, October 1983, September 1989, October 1996, and October 2000.

informed of all risks, and when the research-subject population is itself likely to benefit the results of the experiment. It would be a mistake to view these codes in narrow or procedural terms, when in fact they embody society's profound sense that human beings are not to be treated as experimental guinea pigs for scientific research.<sup>81</sup>

Furthermore, if the profound respect due to an un-implanted embryo requires that experimentation cease at the fourteenth day from fertilization, how would a much more extended series of experiments in uterus be ethically justifiable? These procedures might have as their intended end a desirable purpose, such as the birth of a healthy baby who might otherwise suffer from a severe mitochondrial disorder, but the manner, in which this had become feasible, through a sequence of experiments of this kind, would have been ethically tainted. The end would be subsequently no more justifiable.

## 2. Experimental Use of Human Embryos

The debate over human cloning brought out two different reasons for opposing the experimental use of cloned human embryos in stem cell research process. As mentioned before, some people oppose human embryonic stem cell research on the grounds that the embryo is a person. It is never acceptable to deliberately exploit one innocent human being in order to help another. If the embryo is a person, then harvesting its stem cells in a laboratory is morally

<sup>&</sup>lt;sup>81</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, AN ETHICAL INQUIRY 87-90 (U.S. Government Printing Office, July 2002)

analogous to harvesting organs from babies. Other opponents of human embryonic stem cell research insist that even if this kind of research is necessary and justifiable and uses spared embryos left over from fertility clinics, the laboratory cannot deliberately create human embryos for the sake of research and other experimental purposes.<sup>82</sup>

Furthermore, the notions of parents' right to reproduce and children's right to an open future may justify the enhancement of genetic heritage of a child through techniques of assisted reproduction and genetic engineering. These procedures will undoubtedly involve a series of experimental use of human embryonic stem cells to improve and select the preferred genotypes of the child until it sounds perfect. Defenders of enhancement have seen no moral difference between improving a child's intellectual capacities through education and doing so through genetic alternation. However, even if neither the education nor the genetic alteration violates the child's autonomy, the perfect baby will still be the result of a project not of the infertility doctors, but of the eugenic scientists and their supporters.

# III. Religious Concerns

# A. Dominion and Stewardship over Nature

<sup>&</sup>lt;sup>82</sup> See Frances M. Kamm, *Is There A Problem with Enhancement?* 5 AMERICAN JOURNAL OF BIOETHICS 1-10 (May-June 2005)

According to the Bible, human beings are granted and assigned a dual responsibility by God the Creator: dominion and stewardships. Genesis 1:28 of the Bible states: Human beings, made in the image of God, are to exercise dominion and rule over the fish of the sea and over the birds of the sky and over the cattle and over all the earth, and over every creeping thing that creeps on the earth. This extensive rule sets the human being apart from the rest of creation and from the other creatures. This rulership is translated into the intentional use of animals for human ends and the elevation of human needs and purposes above all other creatures. Since the dominion granted to human beings is not an inherent authority but a delegated rulership, the human beings rule over the animals by the authority of God the Creator. Thus, the theological principle of delegated dominion makes it clear that the stewardship and dominion of other creatures is limited and the rulership shall be exercised only under God the Creator's promise and permission. The human beings shall not take the authority of God the Creator as their own.

#### 1. Disobedience to God the creator's Plan

Consequently, human beings are assigned responsibility for the care, use, and enjoyment of animal creature, but they are not granted license for their mechanistic manipulation, transgenic innovation, or ruthless violation. In the same way, human beings were not commanded or authorized to create new forms of life as extensions of their own designs and images. Being ethical within certain level, animal cloning which uses unnatural means to artificially created or reproduce animal lives may eventually threaten the biodiversity of species that God the Creator clearly intended as a mark of His Creation. Even if the development of animal cloning attributes to provide advances in therapeutic and research technologies which will benefit human beings as well as animals, the cloning technology of this kind may involve redesigns and reshuffles of genetic code and inheritance among animal species and produce the specter of transgenic animals through unnatural means. Since the use of animal cloning technique leads automatically to a sense of engineered life forms as human creations, the technique should therefore not be biblically allowable.<sup>83</sup>

# 2. Cloning Exceeds God the Creator's Intent

As often happens when a powerful new scientific tools is developed, the introduction of mammalian somatic cell nuclear transfer cloning (SCNTC) which plays the most important part of either animal or human cloning technology may possibly generate strong warning that such rulership is beyond the sphere imposed and intended by Cod the Creator. The theological slogan which points out the responsibility of humans exercising dominion over nature is usually invoked as a moral stop sign to advanced scientific research or medical practice on the basis of one or more of the following distinctions between human beings and God the Creator: - Human beings should not probe the fundamental secrets or mysteries of life, which belong to God; -

<sup>&</sup>lt;sup>83</sup> See Albert Mohler, Jr., *The Brave New World of Cloning, A Christian Worldview Perspective*, in HUMAN CLONING RELIGIOUS RESPONSES 92-93 (Ronald Cole-Turner ed., Westminster John Knox Press 1<sup>st</sup> ed., 1997)

Human beings lacks the authority to make certain decisions about the beginning or ending of life. Such decisions are reserved to divine sovereignty; - Human beings are fallible and also tend to evaluate actions according to their narrow, partial, and frequently self-interested perspectives; -Human beings do not have the knowledge, especially knowledge of outcomes of actions, attributed to divine omniscience; - Human beings do not have the power to control the outcomes of actions or processes that is a mark of divine omnipotence.<sup>84</sup> However, the slogan warnings may only be considered as indifferent ethical guidelines to cloning technology as a whole and have not provided sound arguments against contemporary human cloning technology, especially applying to therapeutic and medical purposes.

# **B.** Moral Status of the Human Embryo

The fundamental issue of the beginning of human life appears to have created great tension between science and religion when it comes to embryonic stem cell research. Briefly summarizing, human embryonic stem cells derive from the inner cell mass within an early-stage embryo called a blastocyst, which forms five to six days after conception and approximately a hollow ball of roughly one hundred cells. As development continues, cells of the inner cell mass

<sup>&</sup>lt;sup>84</sup> See National Bioethics Advisory Commission, *Religious Perspectives*, in CLONES AND CLONES, FACTS AND FANTASIES ABOUT HUMAN CLONING 168-169 (Martha C. Nussbaum, Cass R. Sunstein eds., W.W Norton & Company, 1998)

grow and differentiate, ultimately assuming the specialized characteristics of the major organ systems of a human life. If the one-hundred-cell blastocyst which possesses the potential value to human life is a human person, the derivation and use of its cells for therapeutic or medical research may be viewed as a destruction of human life.

Both religious and secular thoughts agree that human life begins at fertilization or conception, yet there are profound controversies among theological perspectives over whether that fertilized egg has the same moral status, i.e., the value of human life, as a child or an adult. In other words, the question about whether the early-stage embryo has full image of God the Creator just as a full-born infant has is much confused and required to be clarified in some ways.

#### 1. Christianity

The Christianity which includes Catholicism and the various Orthodox and Protestant churches lacks a unified and definitive statement on which an embryo becomes a human person. The creation story in Genesis 1:26, which declares that human beings were created in "the image of God," has been read by some to display that the divine imprint has been set on human embryos and that because of this they should be treated as human beings from the moment of conception. This message, according to certain commentators, reveals that all humans, no matter what stage of life, reflect the image of God the Creator.<sup>85</sup>

In term of creation, Genesis 1 indicates that the image of God attaches to that which is human as opposes to animal or plant. As a human child was considered the *tselem* of a parent (Genesis 5), and a *tselem* in the ancient Near East could refer to a statue reminding people of a king's presence, human beings were created to have a special, personal relationship with God the Creator that includes their being God's representative in the world.<sup>86</sup> Accordingly, the Bible speaks of people not only as being in the image of God but also as being the image of God. People are to manifest God the Creator to the world in accordance with the way He has made them and continues to direct them to be.<sup>87</sup>

However, others point out that the creation story features two adults, Adam and Eve, who was fully formed; it makes no mention of human embryos.<sup>88</sup> They note further that the concept of "the image of God" is often understood to refer to the capacity of humans to enter into a relationship with God or to the created character of humans as rational, creative, and moral

<sup>&</sup>lt;sup>85</sup> See Mark J. Hanson, *Cloning for Therapeutic Purposes: Ethical and Policy Considerations*, in HUMAN CLONING: PAPERS FROM A CHURCH CONSULTATION 58-65 (Roger A. Willer ed., Augsburg Fortress 2001)

<sup>&</sup>lt;sup>86</sup> See CLAUS WESTERRMANN, *Genesis 1-11* (John J. Scullion, trans., Augsburg Press, 1984)

<sup>&</sup>lt;sup>87</sup> See C. BEN MITCHELL, EDMUND D. PELLEGRINO, JEAN BETHKE ELSHTAIN, JOHN F. KILNER, & SCOTT B. RAE, BIOTECHNOLOGY AND THE HUMAN GOOD 71-72 (Georgetown University Press, 2007)

<sup>&</sup>lt;sup>88</sup> See Cynthia B. Cohen, *The Image of God, the Eggs of Women, and Therapeutic Cloning*, 32 TOLEDO L. REV. 367-374 (2001)

beings. Thus, the concept applies to already living human beings and neither excluded nor includes early embryos within its compass.<sup>89</sup>

Yet Roman Catholics tend to believe that the embryo obtains full moral status of human person at conception or fertilization and should be treated as human life from the moment of its conception or fertilization. Thus, embryonic stem (ES) cells taken from a viable blastocyst are the most moral objectionable. It is wrong to destroy early human embryos, not only because this amounts to the destruction of a potential human life, but also because this interferes with the process of procreation.<sup>90</sup> The Vatican cites this as the primary reason why it is morally wrong to create or use embryos for stem cell research.<sup>91</sup> However, it is more likely expectable that the Catholic churches have less restrictive views on the use of adult stem (AS) cells, placental blood, or miscarried fetuses, though it does voice concerns regarding stem cell research on embryos that have already been destroyed.

Likewise, the Eastern Orthodox perspective holds that human life and personhood begin with the zygote, whether created *in situ* or *in vitro*, because it can ultimately lead to a human life.

The Eastern Orthodox tradition opposes embryonic stem cell research but accepts such research

<sup>&</sup>lt;sup>89</sup> See Cynthia B. Cohen, Renewing the Stuff of Life, Stem Cells, Ethics, and Public Policy 92-96 (Oxford University Press, 2007)

<sup>&</sup>lt;sup>90</sup> See G. R. Dunstan, *The Moral Status of the Human Embryo: A Tradition Recalled*, 1 JOURNAL OF MEDICAL ETHICS 38-44 (1984); Norman M. Ford, *When Did I Begin? Conception of the Human Individual in History*, in PHILOSOPHY AND SCIENCE 39-51 (Cambridge University Press, 1988)

<sup>&</sup>lt;sup>91</sup> See JOHN PAUL II, TO THE PRESIDENT OF THE UNITED STATES OF AMERICA, H.E. GEORGE WALKER BUSH, 23 July 2001, at www.vatican.va/holy\_father/john\_paul\_ii/speech/2001/july/index.htm

when fetuses from spontaneous miscarriages and not elective abortions are used. Orthodox Christians encourage medical research and support research on discovering alternative sources of stem cells such as adult stem cells. On the other hand, Protestants tend to support embryonic stem cell research because of its potential therapeutic benefit but believe that embryos should not be created for the sole purpose of stem cell research, regardless of the status of the embryos. In sum, Christianity as a whole believes that the zygote has obtained the full moral status of personhood and therefore should not be scarified for research purposes.<sup>92</sup>

## 2. Judaism

Under Judaism, Conservative and Orthodox Judaistic religions differ on the moral status of the embryo forty days post fertilization. It is believed that the fetus is alive before this time but is not a person. Human embryos acquire human status during their developmental process. Hence, its life need not be fully protected. Even after the fortieth day, the fetus does not have full rights until birth. Furthermore, Orthodox Judaism believes forty days after the conception the fetus has moral rights and cannot be aborted unless this is done to protect the health of the mother.

<sup>&</sup>lt;sup>92</sup> See Mahtab Jafari, Fanny Elahi, Saba Ozyurt, & Ted Wrigley, *Religious Perspectives on Embryonic Stem Cell Research, in* FUNDAMENTALS OF THE STEM CELL DEBATE, THE SCIENTIFIC, RELIGIOUS, ETHICAL & POLITICAL ISSUES 82-84 (Kristen Renwick Monroe, Ronald B. Miller & Jerome Tobis eds., University of California Press, 2008)

Whereas in other religions the moral status of embryonic tissue is of paramount importance, in the Jewish tradition this factor is secondary. A pre-implanted embryo may be regarded as a non-ensouled creature that should be respected, but it should not be considered as a human person. Since protecting and saving an existing life is an important Jewish ideal, it may be permissible to use embryonic tissues in stem cell research process, from aborted fetus and from pre-implanted embryos, for therapeutic and research purposes that may potentially cure diseases and result in life-saving efforts. However, the question of whether embryos should be created for the purpose of using their stem cells to save a life still remains unanswered.<sup>93</sup>

# 3. Islamism

Despite the regional diversity in Islamic world, there is relatively little debate among Islamic theological scholars on the moral status of the embryo. Ch. 23:12-14 of the Quran reads: We created man of an extraction of clay, then we sent him, a drop in a safe lodging, then we created of the drop a clot, then we created of the clot a tissue, then we created of the tissue bones, then we covered the bones in flesh; thereafter we produced it as another creature. So bless be God, the best of creators.

According to the Quran, it is suggested that the embryo cannot be perceived as a human being until it has developed further biologically. The Quran does not say exactly when the soul

<sup>&</sup>lt;sup>93</sup> Id., at 84-86

enters the body. However, a Hadith (acts and sayings of the Prophets) says that "the soul is breathed into the body" when the fetus is one hundred twenty days old in the womb. Before that time, the embryo does not have a soul and thus is not a human being, whether growing inside the uterus of a mother, fertilizing in a laboratory dish, or raising under other unnatural environments. As a result, most Islamic scholars have ruled that embryonic stem cell research which terminates embryos within 120 days of conception or fertilization for the sake of life-saving treatments can be supportable.<sup>94</sup>

# C. Dignity of the Cloned

The word "Dignity" is an abstractive and indefinable concept. The central notion etymologically, both in English and in its Latin roots *dignitas* ("worth") and *dingus* ("worthy") is that of worthiness, elevation, honor, nobility, height – in short, of excellence or virtue, suggesting that dignity points to some standard by which people should be viewed and treated. In all meanings it is a term of distinction; dignity is not something that, like a nose or a navel, is to be expected or found in every living human being. Dignity would seem to be, in principle, aristocratic. Though they did not have the term, dignity as honor linked to excellence or virtue would certainly be the view of the ancient Greek.

<sup>&</sup>lt;sup>94</sup> Id., at 86-88

In the historic world of the poets, the true or full human being, the he-man who drew honor and prizes as his dignity, displayed his worthiness in noble and glorious deeds.<sup>95</sup> In the Western philosophical tradition, the most enthusiastic attempt to supply a teaching of universal human dignity belongs to Emanuel Kant (1724-1804), with his doctrines of respect for persons. Based on Kant's moral philosophy of categorical imperative, persons – all persons or rational beings – are deserving of respect not because of some realized excellence of achievement, but because of a universally shared participation in morality and the ability to live under the moral law.<sup>96</sup> Since a cloned child is only a means to make the parents happy, the reproductive cloning violates the basic moral law because the well-being of the cloned child is in fact not its original end and purpose.

### 1. Christian Views

In the Christian tradition, it is widely recognized by theological teachings that all human beings have dignity. Most important reasons that have socialized Christians into taking for granted this thought to the Abrahamic faiths and derive in fact from the Jewish scriptures. The first is the doctrine of the *imago Dei*. Stated in this technical form, of course, it did not become part of the common sense of Christendom. But the idea that human beings are created by God

<sup>&</sup>lt;sup>95</sup> See LEON R. KASS, LIFE, LIBERTY AND THE DEFENSE OF DIGNITY, THE CHALLENGE FOR BIOETHICS 15 (Encounter Books, 2002)

<sup>&</sup>lt;sup>96</sup> Id., at 16

purposefully, with a special relationship to God, and with special privileges in relation to other creatures, took deep hold on the consciousness of Christendom. All human beings are created in the image of God. None are mere animals. Even those who most emphasized the terrible effects of sin on human beings retained the sense that all have importance to God and in selves.

The second element is the commandment to love our neighbors as ourselves. Jesus' explanation of who our neighbors are made it impossible for Christians to read in a restrictive way. Our neighbors are other people regardless of their ethnicity or religious faith or social class. All are to be loved. Such love either responds to an actual dignity in those who are loved, or it attributes dignity to them. Third, Jesus' teaching accents the implication that what is important is how we treat the neighbor. In his parable of the last judgment, the questions asked of those who are being judged have to do only with this. In the Sermon on the Mount, also, what is accented is the universality of love and moral responsibility as well as its radicality. Fourth, in the theological interpretation of Jesus' coming and fate, it is emphasized that Jesus came because of God's love for the whole world and that Jesus' died for all.

And the last, the New Testament uses parental language about God's relation to human beings. God is depicted as the Father of all people, and all human beings are children of God. The Church Fathers borrowed heavily from Greek philosophy, perhaps the most important borrowing was the Platonic and Stoic doctrine of the human soul. This doctrine also supported the view that every human being has a peculiar worth and dignity that cannot be measured by outward conditions. These central and repeatedly emphasized features of the tradition mention above may suffice to explain how self-evident the dignity of human beings had become in Christendom by the time of the Enlightenment.<sup>97</sup>

## 2. Roman Catholic Perspectives

Appeals to human dignity are prominent in Roman Catholic analyses and assessments of the prospects of human cloning, which base "human dignity" on the creation story and on the Christian account of God the Creator's redemption of human beings.<sup>98</sup> The Catholic moral tradition views the cloning of a human being as a violation of human dignity.<sup>99</sup> Religious thinkers generally do not question whether a person created through cloning is a human being created in God the Creator's image. They extend to persons created through cloning the same moral protections they already apply to other persons created in the image of God the Creator.

However, according to some religious opponents, human cloning would violate human dignity because it would jeopardize the personal and unique identity of the clones as well as the person whose genome was thus duplicated. Religious concerns about identity and individuality

<sup>98</sup> See THE NATIONAL BIOETHICS ADVISORY COMMISSION, *Cloning Human Being*, in REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 49 (June 15, 1997)

<sup>&</sup>lt;sup>97</sup> See John B. Cobb Jr., *Human Dignity and Christian Tradition*, 15 August 1990, available at www.religion-online.org/showarticle.asp?title=100

<sup>&</sup>lt;sup>99</sup> See HAAS, J. M., LETTER FROM THE POPE JOHN CENTER, Submitted to the National Bioethical Advisory Commission (31 March 1997)

focus mainly on how persons created through cloning will inevitably or possibly be treated. To treat persons who are the sources of genetic material for cloning or persons who are created through cloning as mere objects, means, or instruments violates the religious principle of human dignity as well as the secular principle of respect for persons. There would doubtless be harder for cloned persons to establish their own identity and for their creators to acknowledge and respect it.<sup>100</sup>

#### 3. Buddhist Thoughts

On the other side, the status of human being is critical within Buddhist thought, because it is the only ontological condition by which an entity can achieve enlightenment and liberation from a world marked by suffering. Basic Buddhist teachings present an ethic of responsibility, centered on the values of non-injury and the relief of suffering of sentient beings, compassion, the no-self, the moral authority of intuition, and reincarnation. These values offer some elements of a Buddhist response to reproductive and genetic technologies, including human cloning. Since human life is a precious opportunity to escape from perpetual rebirth, Buddhist scholars generally agree that the process by which children are born into the world makes no difference. Individuals can begin their lives in many ways, including but not limited to human sexual

<sup>&</sup>lt;sup>100</sup> See ALBERT S. MORACZEWSKI, CLONING AND THE CHURCH, Testimony of the Pope John Center before the National Bioethics Advisory Commission, March 13, 1997; R. E. N. DORFF, HUMAN CLONING: A JEWISH PERSPECTIVE, Testimony before the National Bioethics Commission (14 March 1997)

generation.<sup>101</sup> Any form of technological development that allows for the birth of a human being and the chance human life gives to achieve enlightenment will not degrade the dignity of human nature per se and thus should be equally and especially valuable.<sup>102</sup>

# **D.** Healing of the Sick

Healing of the sick is a sign of the Kingdom of God. Healing was a fundamental component of Jesus' ministry, as witnessed in the gospels. Healing is central to God's identity as disclosed through revelation. Healing is also part of the commission Jesus gives to those he sends out into the world to preach the good news of the kingdom. Healing, therefore, ought to be central to the ways of discipleship and Christian reflection today. The centrality of healing to the mission of Christian discipleship is witnessed not only in Scripture but in the historic commitment of the Roman Catholic tradition to the practice of healing and support of health.<sup>103</sup> Nowhere is this commitment more evident than in the marked presence of Catholic hospitals and allied health care organizations. The origin of hospitals can be traced to Christian practices of caring for the sick, and for centuries communities of religious women and men in the church

<sup>&</sup>lt;sup>101</sup> See DAMIEN KEOWN, BUDDHISM AND BIOETHICS 90 (St. Martin's Press, 1995)

<sup>&</sup>lt;sup>102</sup> See Courtney Campbell, *Buddhism and Cloning*, in THE HUMAN CLONING DEBATE 283-285 (Glenn McGee, Arthur Caplan eds., Berkeley Hills Books, 4<sup>th</sup> ed., 2004)

<sup>&</sup>lt;sup>103</sup> See Therese M. Lysaught, *Human Embryonic Stem Cell Research and the Defense of the Innocent*, in STEM CELL RESEARCH, NEW FRONTIERS IN SCIENCE AND ETHICS 167-168 (Nancy E. Snow ed., University of Notre Dame Press, 2003)

have dedicated themselves to the apostolate of caring for the sick and the dying.<sup>104</sup> Apparently, the Catholic commitment to healing is concretely embodied and enacted in current general perception.

However, the Christian commitment to healing is often obscured or ignored by those who criticize and dismiss Catholic arguments against human embryonic stem cell research. Those who have opposite view to advocate medical research urge that people should have a duty to heal the ill and save lives if they can and to care for the sick if they cannot. Like the Sabbath observance in Jewish religion, it is an overriding a priori duty, taking precedence over other ritual or practical obligations. This obligation is not only a Jewish premise; it is one of the internal and intrinsic goals of medicine and medical research.<sup>105</sup>

#### 1. Who is Matter?

In the embryonic stem cell research, for instance, as it will involve a process in which human embryos are destructed to obtain embryonic stem (ES) cells for medical or research purposes, a human embryo, a researcher, and a patient needing a newly developed treatment are in view. Opponents of embryonic stem cell research with a more biblical perspective will view that three human beings are present. Harvesting of embryonic stem cells could be considered as

<sup>&</sup>lt;sup>104</sup> See Charles Curran, *Roman Catholic Medical Ethics*, in TRANSITION AND TRADITION IN MORAL THEOLOGY 175 (University of Notre Dame Press, 1970)

<sup>&</sup>lt;sup>105</sup> See Laurie Zoloth, *Freedom, Duty, and Limits: The Ethics of Research in Human Stem Cells*, in GOD AND THE EMBRYO, RELIGIOUS VOICES ON STEM CELLS AND CLONING 146 (Brent Waters, Ronald Cole-Turner eds., Georgetown University Press, 2003)

a form of murder. Since there are only two human beings with the ability to choose, the researcher's and patient's wishes of course prevail. Thus, a greater violation would be done by fatally injuring the embryonic child. Why should the embryonic child involuntarily sacrifice his or her life to heal the other in need?

#### 2. Sacrificing One Life for Another

Most religions believe that embryos are alive. Once an egg is fertilized, it will, unless interfered with, develop into a fully-developed adult. By sacrificing embryos for embryonic stem cell research, scientists are sacrificing one certain life for the potential benefit of another. That one life they are sacrificing could be the next Beethoven or the next Einstein. Human life is inherently valuable and dismissing the ethical implications of embryo destruction devalues human life. Thus, the use of embryonic stem cells in therapies may in itself be fundamentally flawed.

# IV. Conclusion

Not everything that can be done should be done. The technological imperative, encouraging the continuing pioneering of new techniques, must be checked by the moral imperative, requiring that such techniques should be achieved by ethically acceptable means and employed for ethically acceptable ends. The search for wise decisions must involve the relevant scientific experts, but it cannot be delegated to them alone. There must be other parties in the debate, which centers on the nature of the respect for human life and human dignity. Theology, with its insight that the will of God the Creator is always the true origin of all value, may play an important role to make critical contribution here. Theology will not seek to suppress advances that could benefit humankind in acceptable ways, but it will insist that the means by which these desirable ends are achieved must themselves be of ethical integrity.

It should be noted in life science that the more powerful the methods we use, the more we need to consider not only what is possible for humanity, but what is happening to us as people if we say yea to every possibility which science may make possible. To be answerable to God the Creator for the way we use, current society as a whole has two important implications. One is in the sphere of human relationships with each other, and the other arises from God's ordinance to care for the rest of creation. On both these counts, not all technical progress in biotechnology is necessarily desirable. A sense of restraint may be needed.

Dignity should stand a significant situation in many bioethical debates. The language of human dignity is persuasive to many, and it can provide welcome common ground for mobilizing consensus in the public arena. At some point in certain debates, however, when concepts of human dignity irreconcilably conflict, it will be necessary to look at the relative merits of those concepts. Not surprisingly, human cloning has until now received little serious and careful ethical attention because it was typically dismissed as science fiction, and it is in fact difficult to articulate, uneasy to realize and even repugnant to many people. Thus, any assessment of human cloning technology based on moral perspectives must be carefully provided at this point.

In addition, much of the debate surrounding embryonic stem (ES) cells has centered on the ethical and moral questions raised by the use of human embryos in medical research. In contrast to the widely divergent public opinions regarding this research, it is largely assumed that from the perspective of science there is little or no debate on the matter. The scientific merit of stem cell research is most commonly characterized as indisputable and the support of the scientific community as unanimous. However, nothing could be further from the truth. While the scientific advantages and potential medical application of embryonic stem cells have received considerable attention in the public media, the equally compelling scientific and medical disadvantages of transplanting embryonic stem cells or their derivatives into patients should have been cautiously regarded as well.

# Chapter 3

# Legal and Policy Aspects on Human Cloning Technology

# I. Introduction

After Dolly the Sheep was announced to be successfully produced through cloning technique in February of 1997, the novel technique known as "somatic cell nuclear transfer (SCNT)" and used by Dr. Ian Wilmut needs to be distinguished from an older and very different technique known as "embryo splitting" or "twinning." In SCNT technique, Dr. Wilmut took a somatic cell from an adult sheep, and in effect took its nucleus with the genetic instructions contained in the DNA, and inserted it into an egg cell of a different sheep from which the nucleus had been removed. He then was able to stimulate the asexually resulting cell and get it to begin dividing and become a nascent embryo. The eventual result of those divisions, after implanting this embryo in a sheep's uterus, was Dolly.

The technique is much unlike to the embryo-splitting or twinning technique. In embryosplitting technique, on the other hand, scientists take a bisexually fertilized egg after it begins to
divide with the help of *in vitro* fertilization, and split the cells apart after one division. For the first few divisions, all of the cells are essentially identical. Thus, each one may theoretically continue to divide on its own and become a separate embryo. It indeed creates a clone of an embryo. This is exactly what happens naturally when identical twins are created. Should these two kinds of techniques mentioned above be similarly treated and regulated? What kind of cloning that should be cautiously controlled?

To illuminate these questions, the term "cloning" should first be clarified in certain way. Unfortunately, the term "cloning" is quiet an ambiguous one to scientists, scholars, and the public, since it can refer to various genetic-duplicating processes. As is well known, many plants can clone themselves, and have presumably been doing so since life began. Generally speaking, cloning may be understood in a sense where it is defined as asexually producing a cell or organism with the same nuclear genome as the donating cell or organism.<sup>106</sup> This definition assumes that, in this type of cloning, the entire genetic identity of an individual is copied. This is not strictly true enough, though. For example, when Dolly was formed, she inherited not only the genetic material in the parental nucleus but also the small amount of DNA called mitochondrial DNA (m-DNA) existing outside the nucleus of each cell and which in this case

<sup>&</sup>lt;sup>106</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 59-60 (U.S. Government Printing Office 2002)

came from the donor egg. Accordingly, the definition of cloning used above is not entirely perfect. Nevertheless, the definition does make clear the general type of cloning to which it applies to most part of contemporary human cloning technology.

In addition, a distinction of cloning is sometimes drawn between its related techniques for reproductive and therapeutic purposes. It seems likely that discussion of the legal and policy issues will increasingly focus around them. Reproductive cloning is where the intent is to produce more or less identical fetuses and babies and where the egg is implanted into the mother. Therapeutic cloning, by contrast, could be where stem cell lines are developed with a view to medical application. The nucleus of a cell donated by one person would be transferred to an egg mother cell or an oocyte and the embryo would be grown to generate stem cells which could be induced to form whichever type of cell or tissue was required for therapeutic purposes, such as brain tissue, muscle or skin. The essential difference is that here the object would not be to produce another human being but to treat an existing human being as a source of spare parts for another. However, the distinction between reproductive and therapeutic cloning may still be arbitrary.

To address legal arguments on the merits, it is important to seek terminology that most accurately conveys the descriptive reality of human cloning technology. Thus, cloning may be redefined as the process related to the SCNT technique, the reproductive cloning may be renamed as cloning-to-produce-children, and the therapeutic cloning may be renamed as cloningfor-biomedical-research. However, none of the terms available is entirely trouble-free to best describe the facts of the matter. Since human cloning has enormous legal implications, the government cannot consider it as an ordinary matter and deal with it by simply passing regulations without thoughtful discussion and deliberation. It requires researchers and the public to help policymakers decide whether and how human cloning technologies should be regulated by the government.

Before the cutting-edge human cloning technology becomes a commonly used application either in reproductive or in biomedical purpose, researchers, policymakers, as well as the public should have a joint responsibility to explore the potential effects of contemporary cloning-related technologies on human lives so that the global village can make informed decisions for human good as a whole. This chapter will examine the possible legal implications of human cloning technology to the modern world. Serious benefits and risks resulted directly or indirectly from this novel biotechnology will also be carefully reviewed so as to consider a feasible policy approach to bravely face and effectively utilize it.

# II. Legal Aspects

## A. Violation of Human Dignity

As mentioned before, human cloning technology would breach a human's fundamental right to individuality. Thus, by allowing cloning to produce children, humanity would be forgoing the intrinsic knowledge that each person is new and unique, not predetermined, prejudged by what has gone before or after, each person. If there is a fundamental right to individuality, then the human cloning technology of this kind will indeed breach that right and consequently insult the human dignity as a whole. Although many people may have different ideas on what constitutes human dignity, and dignity alone should not be able to provide a concrete solution to most controversial challenges raised by scientific advances such as human cloning technology, the extent of the right to individuality should be defined clearly without a doubt.<sup>107</sup>

## 1. Self-worth of the Cloned

With regard to the welfare of the human clones, the reproductive human cloning technology would also involve the denial of the right to an open future of a clone. A cloned

<sup>&</sup>lt;sup>107</sup> See B. Gogarty, What Exactly Is An Exact Copy? And Why It Matters When Trying To Ban Human Reproductive Cloning in Australia, 29 JOURNAL OF MEDICAL ETHICS 84-89 (2003)

child might be constantly compared to the donating adult from whom he was cloned, and thereby burdened with oppressive expectations. The parents might actually limit the cloned child's opportunities for growth and development for his or her entire life. Even if disregarding the parent's conduct or attitudes, a cloned child might still be encumbered by the thought that he or she is only a copy of the donating adult and not an original one. Consequently, the child's right of self-worth or self-dignity would be difficult to sustain.<sup>108</sup>

### 2. Self-decision of An Individual

However, it is notable that procreative freedom has long been recognized as one of fundamental rights and become part of the concept of human dignity deserving of special protection.<sup>109</sup> If a man who cannot produce or has no functional sperm or a woman who cannot produce or has no functional eggs, and the sexual reproduction is not possible even with the benefit of *in vitro* fertilization, he or she could still produce offspring by reproductive cloning if this technology develops to the point at which it is safe and effective.

Thus, the reproductive freedom should implicate the right to employ human cloning technology for reproducing offspring, at least for infertile men and women who cannot reproduce

<sup>108</sup> See Robert Wachbroit, *Genetic Encores: The Ethics of Human Cloning*, REPORT FROM THE INSTITUTE OF PHILOSOPHY & PUBLIC POLICY, also available at www.publicpolicy.umd.edu/IPPP/Fall97Report/cloning.htm Based on the words of Kant, dignity means that people must always be treated as an end in themselves and never only as a means. See Kant I. Grundlegung *zur Metaphysik der Sitten*. [Foundations of the Metaphysics of Morals] Berlin: Akademie-Ausgabe, 1911. In German

<sup>&</sup>lt;sup>109</sup> See Skinner v. Oklahoma, 316 U.S. 535 (1942)

sexually.<sup>110</sup> From this point of view, the prohibition of human cloning must be seen as an intervention in a couple or a would-be single parent's right.<sup>111</sup> If it is true, then the government may not infringe on the fundamental right to reproduce offspring by human cloning technology unless a compelling state interest is found in support of that governmental action.<sup>112</sup>

## 3. Equal Treatment to All

Here may thus raise the question of the prioritization among individual's interests. Since human dignity is the core of the right of self-determination, undoubtedly recognized by the international community and most developed and many developing countries in the world, it should include the mechanism to protect the individual's self-decision for accessing to the reproductive cloning techniques. Therefore, it may be improper and disproportional to sweepingly prohibit any individual under his or her free will to reproduce through human cloning technology without any exception such as an infertile couple.<sup>113</sup>

Moreover, the well-known Declaration of Independence clearly states, "All men are created equal." Article 1 of the Universal Declaration of Human Rights (UDHR) also describes,

<sup>&</sup>lt;sup>110</sup> See, e.g., Mark D. Eibert, *Human Cloning: Myths, Medical Benefits and Constitutional Rights,* 53 HASTINGS L. J. 1097 (2002)

<sup>&</sup>lt;sup>111</sup> See Wu, Family Planning through Human Cloning: Is There a Fundamental Right? 98 COLUMBIA L. REV. 1461 (1998)

<sup>&</sup>lt;sup>112</sup> See KERRY LYNN MACINTOSH, ILLEGAL BEINGS: HUMAN CLONING AND THE LAW 112-115 (Cambridge University Press, 2005)

<sup>&</sup>lt;sup>113</sup> See Tade Matthias Spranger, What Is Wrong about Human Reproductive Cloning? A Legal Perspective, 11 EUBIOS JOURNAL OF ASIAN AND INTERNATIONAL BIOETHICS 101-102 (2001)

"All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." If a government deliberately treats human clones differently from humans born through sexual reproduction, then it may violate the equal protection guarantee under fundamental norms of many civilized nations.

Although there is a political consensus that reproductive cloning is wrong, there are no rules so far that specifically prohibit or ban the cloning of human beings. Supposed in the near future a law prohibits scientists, doctors, parents, or any other persons from performing or participating in human cloning and tries to prevent any birth of human clones, or only bans reproductive cloning but has the effect and purpose of preventing any birth and existence of certain human clones, while at the same time it does not prohibit or restrict sexual reproduction, then the law in question will have a disparate impact on human clones, treating them less favorably than human born through sexual reproduction. This result would trigger the protection of human dignity of all created persons and the concern of the equal treatment guarantee between cloned persons and non-cloned persons.<sup>114</sup>

# **B.** Exploitation of People's Autonomy

<sup>&</sup>lt;sup>114</sup> Id., at 154-161

The word autonomy comes from two Greek words, auto (meaning "self") and nomos (meaning "law"). The core idea of autonomy, self-rule or self-governance, can have many levels and interpretations. In the context of ethics, appeals to autonomy literally signify that the self is its own ethical law that it generates its own standards of right and wrong. Anyone whose acts are motivated by environmental or third-party control is not autonomous to that extent. However, autonomy is not merely matter of acting on "one's own" first-order beliefs and desires; those motivational states must reflect or be in harmony with the higher-order values the ethical law has or would endorse. For example, a drug addict can satisfy his or her own strong desire for a quick fix, if nobody interferes with him or her. But he or she may have a second-order wish that his or her first-order desire for drug would not be efficacious. Although under an autonomy-based approach there is no encouragement in this way of looking at the world to consider the wellbeing of others, the higher-order values may lead his or her autonomy to be greater to the extent more aspects of his life exhibit integrity around not only individual acts, but also his or her occupation, character, relationships, and sensibilities.

## 1. Autonomous Choices

Likewise, there will be deemed no serious legal problems if the self should respect the autonomy and well-being of others while it makes its autonomous choices happen to have good moral character. However, when the autonomous state of mind predisposes the self to be unconcerned about how its actions will affect others, the self may become selfish and reckless and its decision may be dangerous or perilous to others' freedoms and advantages. In other words, here may have other ethical and legal considerations that can be more important than people's autonomy.<sup>115</sup> In addition, protecting people's autonomous choices may be all right only if all people are in a comparable position to make their own similar choices. Where some people are in a very weak position economically, socially, or even physically, they may not be able to avail themselves of the same opportunities. Thus, with certain mandate to love others sacrificially may have forced people to use their autonomous choices to further the interests of others. On the other hand, the self-centeredness of an autonomy outlook has also been gradually eradicated from public policy to public life.

## 2. Thoughtful Evaluation of Autonomy in Cloning

Therefore, an honest, complete autonomy-based evaluation of human cloning would have to consider the autonomy of all persons involved, including the people produced through cloning, and not just the autonomy of researchers and people who desire to have clones in any kind. If the autonomy of the clones should be seriously taken into consideration, at least two situations should be observed here.

<sup>&</sup>lt;sup>115</sup> See J. Dyck, *Lessons from Nuremburg*, in ETHICS IN MEDICINE (Jay Hollman, John Kilner eds., Bridge Publications, 1999)

First, human cloning would involve a grave risk to the clone's life. In the process of cloning the sheep Dolly, two hundred and seventy-six failed attempts occurred, including the death of several so-called defective clones. Likewise, there is no plausible way to undertake human cloning at this point without a major loss of human life. Even in a process which involves transferring the genetic material from each of the cells in an early-stage embryo to other egg cells to attempt to produce identical clones, a mass destruction of human embryonic life cannot be preventable. Typically, there is no significant therapeutic benefit to the clone in the many scenarios for which any cloning practice has been proposed. Since it is impossible to obtain the clone's consent to be brought into a cloning process, unless the biomedical benefit to the clone so huge as to outweigh the substantial likelihood of the death or deformity that occurred in the Dolly or similar experiments, the tragedy that happens because of the exploitation of the autonomy of any existing human being would involve a substantial infringement on the autonomy of all kinds of the clones produced through this cloning procedure.

Second, human cloning would conflict with the autonomy of the clones. It would radically weaken the family structure and relationships of the clone and therefore be fundamentally at odds with their most basic freedoms and interests. Are the children who result from cloning really the siblings or the children of their parents? Is the donor of the genetic material logically and physically be the parent of the clone? What about the donor of the egg into which the genetic material is inserted? Who will provide the necessary love and care for the damaged or discarded embryos or fetuses which fail to develop, or the cloned infants or children who lose their life after birth or suffer deformed diseases, resulted from inaccuracies or mistakes made by the scientists who manipulate the cloning process for either experimental or reproductive purpose? Regardless of any future legal resolutions of such matters, child clones would undoubtedly experience mystification about their psychological and societal relationships, and even worse, their very sense of identity. Packs of legal entanglements, including the issue of the clone's inheriting title, would also arise simultaneously. Accordingly, human cloning may swell the autonomy of the person who produces the clone; it may also disgrace the autonomy of the clone at the same time.<sup>116</sup>

## C. Commoditization of Human Organs

Most pro-life supporters believe that an embryo is a living human person. During embryo cloning, they would be subjected to assault with the possibility of being murdered. Furthermore, cloning could produce a reservoir of "spare parts." Fertilized ova could be cloned into multiple zygotes; one could be implanted in the woman and allowed to develop into a normal baby; the other zygotes could be frozen for future use. In the event that the child

<sup>&</sup>lt;sup>116</sup> See John F. Kilner, Human Cloning, at Http://www.cbhd.org/resources/cloning/kilner\_2002-11-15.htm

required a bone marrow transplant, one of the zygotes could be taken out of storage, implanted, allowed to mature to a baby and then contribute some of its spare bone marrow to its (earlier) identical twin. However, at this point, the embryos would be treated as a commodity to be exploited, not as a person.

Furthermore, cloning to gain embryonic stem cells for research or tissue transplantation purposes requires the sacrifice of the clonal embryo in order to obtain these cells. Creating and then destroying human life in this way is an abuse of power and control because embryos, even at this early stage of development, are deserving of special respect as human wholes. Thus, the very idea of creating and using human organs for "spare part" manufacture should be repugnant. The push for human cloning comes from researchers and the biotechnical industry which stands to profit from the freedom to carry out human cloning research. The "industrial production" mentality in which human life is used for its tissue is dangerous, reducing the tiniest and most vulnerable members of the human family to mere "commodities." Human beings should not become a commodity, and commercial interest inhuman cloning should be withstood.

#### 1. Human Eggs As Research Supplies

If human cloning is permitted for any purpose, no matter how specific, there will be pressure on IVF clinics to produce more "spare embryos," and on women to donate eggs and to offer their wombs as incubators. As we knew in the description of SCNT, each attempt at cloning requires one egg. Even more, human cloning is very difficult and will take a long time to perfect. There is a serious potential for coercion. Many more eggs would be necessary in order to clone, as compared to IVF. For cloning research to really take off, scientists will need tens of thousands of human eggs. However, eggs are rare and currently not easy to obtain. It requires that egg suppliers undergo an onerous and sometimes dangerous procedure known as super-ovulation in which a woman of child-bearing years is injected with high doses of hormones so that her ovaries release ten to twenty eggs in a cycle, instead of the usual one. These eggs are then removed with a needle inserted through the vaginal wall.

This procedure is not only uncomfortable, but it can also be risky. About 5 percent of women who undergo super-ovulation experience serious side effect, such as infection, infertility, paralysis, loss of limbs (due to blood clots), and even death. Since that would be gravely burdensome to the potential oocyte donors, what manners and protections should be required for them? In addition, how can one ensure fully informed and voluntary consent for them? Should they be compensated or remembered for donating their organs for this kind of research or therapy?

### 2. Market for Human Eggs

Given these dangers, few women volunteer are readily to become egg donors. As a consequence, some researchers argue that they should be authorized to buy eggs from women.

Feminists and others object, worrying that eggs markets will exploit poor or indigent women who, unlike their better-off sisters, will be enticed to risk their lives, health, and fecundity so that the human eggs can become commodities and the agents or institutions dealing with human organ transaction may obtain indecent profits and take undue advantage of the exploration of modern human cloning technologies. This new issue involves two major questions. First, what are the long-term effects on a woman who sells her eggs? Harvesting eggs is not as natural as does for sperms. Second, should a woman be able to sell her eggs in the same way other people sell their organs, such as kidneys, as a part of her body with which she's free to do as she chooses?

"We're not going to know all the effects of women selling their eggs for at least ten years or more," noted Jane Orient, M.D., executive director of the Association of American Physicians and Surgeons. "We don't know the long-term consequences of the powerful drugs and surgery [necessary] to obtain the eggs. How many women are selling their chances of motherhood for a few thousand dollars?" Egg brokers charge around \$16,500 per egg, which includes a fee of \$4,000 or more for the egg donor. A donor must inject herself with fertility drugs every day for six weeks, and a woman who has successfully produced eggs three or four times can receive up to \$8,000. Some of these agencies offer their customers photographs and information about donors' hobbies, education, and religion, along with health screening, so customers can pick their donor. Other agencies consider "donor shopping" for "designer babies" unethical; they assign a donor on the basis of a few genetic traits.

Some of the embryos that were created were implanted through IVF procedure, and some were frozen. Some clients have held a newborn in their arms and said, "I don't feel attached to my child," according to University of Minnesota Psychologist Linda Hammer Burns. In some cases, parents divorcing years after the children are born use the means of their conception as emotional weapons in bitter legal fights. Apparently, the outcome of these "miracles for sale" is not always as happy as expected by the scientists and researchers who advocate the pro-choicely reproductive rights.<sup>117</sup> Thus, the right for pursuing happiness to have a baby should be better realized through some other more natural or less artificial means.

### 3. Clone as Organ Donors

Human cloning technology may also potentially used to create a person with tissues immunologically matched to an existing individual. If the technology uses somatic cell nuclear transfer (SCNT) for cell or tissue production without creating a human being, then this situation may be less controversial in some extent. Nevertheless, does the immunologic tolerance of stem cells produced by biomedical cloning technology justify this technique to obtain genetically

<sup>&</sup>lt;sup>117</sup> See Michael Arnold Glueck, M.D., *Emerging Human Embryo Market Poses Moral and Ethical Dilemmas,* HEALTH CARE NEWS, at http://www.heartland.org/policybot/results/23042/

identical stem cells for the purpose of medical treatment? It is notable that medical ethics is ground in the principle of non-maleficence, on the avoidance of harm. Any involvement by a physician in the deliberate sacrifice or harm of children in order to harvest organs would violate this axiom. Furthermore, the ethical prohibition against using human beings merely as means rather than as ends in them would also make the possibility of using human cloning to create an organ donor highly debatable.<sup>118</sup>

## **D. Illegitimacy of Cloning Process**

As indicated by many scientific statistics, a very large percentage of cloning efforts end in failure and clones that do survive often have fatal or deform problems in their genes. Dr. Ian Wilmut, one of co-creators of Dolly, has even said that human cloning projects would be criminally irresponsible. Cloning technology is still in its early stages, and nearly 98 percent of cloning efforts end in failure. The embryos are either not suitable for implanting into the uterus or they die sometime during gestation or shortly after birth. Those surviving clones wind up suffering from fatal or problematic genetic abnormalities. Some clones have been born with defective hearts, lung problems, diabetes, blood vessel problems, and malfunctioning immune

<sup>&</sup>lt;sup>118</sup> See AMA, *The Ethic of Human Cloning*, 98 REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS OF THE AMERICAN MEDICAL ASSOCIATION 4, available at www.ama-assn.org/ama1/pub/upload/mm/369/report98.pdf

systems. One of the more famous cases was a cloned sheep that was born but suffered from chronic hyperventilation caused by malformed arteries leading to the lungs. Opponents of cloning point out that while we can euthanize defective clones of other animals, it's morally problematic if this happens during the human cloning process.<sup>119</sup>

### 1. Wrongful Use of Cloning

Furthermore, a cell many years old from which a person is cloned could have accumulated genetic mutations during its years in another adult that could give the resulting clone a predisposition to cancer or to other diseases of aging. Therefore, the human cloning technology, at least in reproductive cloning, would essentially be equivalent to intentionally creating malformed, genetically defective children, which would presumably either be aborted at their fetus stage or live with very short or uncomfortable lives with windless soreness and suffering.<sup>120</sup> The process for carrying out human cloning at this point may legally lack of legitimate purpose and thus be morally impermissible.

Even if we allow cloning for research purposes, in order to enhance our genetic structures not only to rid ourselves of genetic defects, i.e., negative eugenics or negative engineering, but to create better and healthy lives, i.e., positive eugenics or positive genetic engineering, theses

<sup>&</sup>lt;sup>119</sup> See Kevin Bonsor & Cristen Conger, *How Human Cloning Will Work*, available at http://science.howstuffworks .com/human-cloning3.htm

<sup>&</sup>lt;sup>120</sup> See Dan W. Brock, *Cloning Human Beings: An Assessment of the Ethical Issues Pro and Cons*, in CONTEMPORARY ISSUES IN BIOETHICS 600 (Tom L. Beauchamp, LeRoy Walter eds., Wadsworth Cengage Learning Inc. 6<sup>th</sup> ed., 2003)

technologies would still threaten to distort and ultimately eliminate the line between therapy and enhancement. We may have all the good intentions in the world, but in the process we stand to lose the very means by which to judge the goodness or the wisdom of the particular aims proposed by a positive eugenics.<sup>121</sup> Thus, human cloning for research purposes may be morally impermissible, either.

## 2. Disproportionate Use of Human Embryonic Cell

Stem cells may have potential of being used in research and eventually medical or therapeutic cloning. At a more basic research level, stem cells can assist in understanding how organs form, why cells die, and why tissues are rejected when transplanted. Through genetic manipulation, stem cells can also be used to deliver genes or proteins in gene therapy. Stem cells probably exist in all human organs, but are easily found in the inner portion of the blastocyst where a globular group of cells that has the potential to differentiate into an embryo. The second source of stem cells with multi-potent potentials is umbilical blood. These cells have been used to treat hematological disorders. The third source of stem cells is the umbilical cord itself. When these cells are placed into the blood stream in animal models, they appear to migrate to the brain and may become useful in treating traumatic brain injury and stroke. The fourth source of stem cells that derived from adult tissues has currently been unknown.

<sup>&</sup>lt;sup>121</sup> See PRESIDENT'S COUNCIL ON BIOETHICS, Arguments against Reproductive Cloning, in STAFF WORKING PAPER 3B (January 2002), also available at http://www.bioethics.gov/background/workpaper3b.html

Based on this analysis, human embryonic stem cells appear to have the most potential. There are four sources of these cells: embryonic stem cell lines already established, embryos created by couples through assisted reproductive technologies (ART), embryos created through somatic cell nuclear transfer (SCNT), and embryos created through parthenogenesis technologies (PT). SCNT is the preferred technique in producing embryonic stem cells because they can be administered to the donor of the nucleus without eliciting an immune response. SCNT is the technique that is successfully used in cloning animals. However, there is no support in the scientific community for using SCNT for cloning of human beings.

Even more, despite the enormous potential that stem cell research offers, there are objections and concerns about pursing this line of research, especially when it involves human embryonic stem cells.<sup>122</sup> Does the potential of biomedical therapy to cure many diseases or replace damaged organs justify destruction of blastocyst having great potential to develop to a normal person to obtain stem cells only for biomedical research or therapy? Indeed, the question of what kind of human cloning research would be compatible with ethical and legal requirements for the use of human subjects in research is still an unsolved maze that is complex, controversial, and largely unexplored. However, the novelty and hopefulness of these techniques does not mean that there are not legitimate issues that have to be addressed before proceeding forward.

<sup>&</sup>lt;sup>122</sup> See O.Edwin McClusky, *Stem Cell Research*, in REPORT OF COUNCIL ON SCIENTIFIC AFFAIRS: STEM CELL RESEARCH, CSA REPORT 3-A-04 (April 29, 2005), also available at http://www.texmed.org/Template.espx?id=2704

Practices considered seriously wrong and harmful to the human may be deemed outlawed by most civilized communities. If stem cells from any source other than embryos may be found to have the same potential as embryonic stem cells, the use of those cells will be preferred and the use of embryonic cells shall be seriously reevaluated.

# **III.** Policy Aspects

## A. Common Good

## 1. Scientific Inquiry

Although human cloning technology is still in its immature stage, tremendous debates have already wobbled the world of science. The courts of many countries have given their judgments banning human cloning and many religious entities have raised strong opposition against it. However, the freedom of scientific inquiry and the right to acquire knowledge are guaranteed by the constitutions of most civilized nations and major documents of the international community as well. Furthermore, scientific theories have historically been protected because of the immense importance to explore human intelligence and advance human life. Like most scientists, biomedical scientists have ambitions to explore the living nature and provide relief in humanity's pursuit of health, happiness, and comfort. Therefore, scientific inquiry is sometimes views as a public good. Would banning human cloning of any kind violate the right to scientific inquiry? Should an unrestricted scientific inquiry be permitted and encouraged to the greatest extent? Should they outweigh the common values persisted and maintained by the society?

There is a well-acceptable principle that the guaranteed liberty is protected only if it does not disturb others and the norms of the society. Scientists do not have the unqualified freedom to pursue whatever inquires they think fit. To the contrary, based on the bottom line mentioned above, the research for scientific inquiry may be constitutionally restricted when the government has rational basis for regulation. The right to scientific inquiry must yield to conflicting rights or moral principles at times.<sup>123</sup> The freedom of scientific inquiry is apparently subject to this maxim. In other words, a restriction to the freedom of scientific inquiry may be made if any human welfare and human rights protected by the society would consequently suffer.<sup>124</sup> Therefore, subject to the corroboration of social justice, the freedom of scientific inquiry may sometimes give way to preponderant human rights and imperative moral obligations.

If human cloning technology succeeded and if it were practiced in certain extent, the questions of whether cloning research or other related research, inquiry, or scientific

<sup>&</sup>lt;sup>123</sup> See Adam Gusman, An Appropriate Legislative Response to Cloning for Biomedical Research: The Case Against A Criminal Ban, 14 ANNALS HEALTH L. 361, 368 (2005)

<sup>&</sup>lt;sup>124</sup> See SOFIA GRUSKIN, MICHAEL A. GRODIN, GEORGE J. ANNAS, PERSPECTIVES ON HEALTH AND HUMAN RIGHTS 175 (Routledge Taylor and Francis Group, 2005)

communication are also to be protected, and to what degree should be seriously considered. The decision makers have to decide how best to balance governmental interest ensuring the freedoms of inquiry and research of the scientists and academic scholars and the possible benefits their research might contribute to the well-being of the people against the need to protect the people from any physical, emotional, or societal risks or dangers occurred from the introduction of this novel technology. The advent of human cloning technology presents the inevitability of novel and significant social changes, thus, a balance among competing rights and interests would be indicated as then social justice is contour.

#### 2. Social Justice

In addition, stem cell research raises considerable questions of justice, both in basic research and in the application of the research. Does the research is truly helpful to create a world that is more just? The principle of justice should place a priority on the public aspects of this research. An injustice may occur when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Since human stem cell research indicates great potential benefits to the humans, it should be noted that the benefits may be

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distributed unjustly and further privilege the moneyed and powerful persons at the expense of those on the socioeconomic margins.<sup>125</sup>

Fortunately, the principle of justice could be further conceived where the equals be treated substantially equally.<sup>126</sup> If the ethical principles such as "equivalent attention to the vulnerable" and "an equal commitment to solidarity" are the core values of a society, then stem cell research may be structured so that it is directed to helping the vulnerable and to improve the essential social contract of a community. Therefore, all research related to stem cells must at least aim at increasing access to basic, decent health care which is universally available to the general population.<sup>127</sup> Thus, a strong stand on permitting embryonic research to proceed by a broad consensus of the scientific community would not take place until the promise of stem cell research becomes significant and appreciated.

## **B.** Legalization

## 1. Legislation

<sup>&</sup>lt;sup>125</sup> See Margaret R. McLean, *Stem Cells: Shaping the Future in Public Policy*, in THE HUMAN EMBRYONIC STEM CELL DEBATE 197, 202 (Suzanne Holland, Karen Lebacqz, and Laurie Zoloth, eds., The MIT Press, 2001) <sup>126</sup> See JONATHAN BARON, AGAINST BIOETHICS 15 (The MIT Press, 2006)

<sup>&</sup>lt;sup>127</sup> See Laurie Zoloth, *Freedom, Duties, and Limits: The Ethics of Research in Human stem Cells*, in GOD AND THE EMBRYO, RELIGIOUS VOICES ON STEM CELLS AND CLONING 141, 145 (Brent Waters and Ronald Cole-Turner eds., Georgetown University Press, 2003)

Generally speaking, there are still no clear-cut laws governing all forms of the cloning of human beings. As a matter of fact, the practice of human cloning technology may not be straightforwardly outlawed in certain areas. Actually, at least one court in the United States has recognized that there is a constitutional right to clone which lies at the very heart of the constitutional right of "privacy."<sup>128</sup> Policies and laws are currently being formulated in different countries. Some countries have already banned any kind of human cloning technology or only human reproductive cloning but given permission to clone human embryos for medical research, while other countries have still struggled with political debates and have not yet passed any substantive laws regarding banning or restricting the development of human cloning technology.

In addition, policy and law may also influence the potential funding resources for supporting the advanced development of human cloning technology in certain nation or region. For example, Bush Administration is always reluctant to justify the stem cell research in the U.S. As a result, the public fund may not legally grant for serving this research in any sense. Since the private fund may not sufficiently afford the expenditures for stem cell research, the research team or institution may be forced to go abroad to seek for other supporting resources from countries that approve the research efforts in human cloning technology.

<sup>&</sup>lt;sup>128</sup> See, e.g., Kristina Martin and Ronald Martin, et al. v. Martin Ballinger, Secretary of Health and Human Service, et al., on Petition for Writ of Certiorari to the U.S. Court of Appeals for the Eight Circuit, No. 99-1099

Although vast majority of researchers repudiate reproductive human cloning technique, at least two fertility doctors – one in the U.S., the other in Italy – have claimed to attempt cloning humans. It is possible that the world might see its first cloned humans before it sees its first approved therapies from embryonic stem cells. Or even more, if human cloning is allowed someday, effective governmental controls will then need to be well established to ensure rightful compliance.

## 2. Regulation

Furthermore, there are arguments raised in reference to human cloning technology that involve formulating legislation versus regulation. Those who support the need for legislation insist that legislation is sufficiently proscriptive and sufficiently proactive; a regime with adequate power and jurisdictional reach, to ensure that it cannot be circumvented or undermined.<sup>129</sup> On the other hand, those who argue regulation rather than legislation assert that any single piece of legislation will be deemed too strict by some and too lenient by others.

However, a single law cannot adapt to the changing nature of science. A law may be too narrow-tailored, prohibiting valuable or controversial research. A law might be too lenient, allowing human cloning research to circumvent the regulation.<sup>130</sup> However, no matter whether

<sup>&</sup>lt;sup>129</sup> See B. Gogarty, What Exactly Is An Exact Copy? And Why It Matters When Trying To Ban Human Reproductive Cloning in Australia, 29 JOURNAL OF MEDICAL ETHICS 84-89 (2003)

<sup>&</sup>lt;sup>130</sup> See Adam Greene, *The World after Dolly: International Regulation of Human Cloning*, 33 GEO. WASH. INTL. L. REV. 341-62 (2001)

legislation or regulation to be preferred by a specific community, some sort of adequate controls need to be in place prior to fully allowing the development of human cloning technology in any kind. Current regulations concerning reproductive human cloning or even therapeutic stem cell cloning are vague and unclear. This makes it difficult for hospitals, universities and other public-funded or private research institutions to tell if they are in compliance.

The opinion of Stanford University General Counsel Debra Zumwalt is that regulation should be based on science and good policy rather than politics. As a result, she favors overall policy being set by the legislature with details being worked out at the administrative level by regulatory agencies with expertise. But she warns that regulation developed by a local government should not be more restrictive than the regulation set up by its central government, or the human cloning related research practice would be driven out of control.<sup>131</sup>

## 3. Minimum Standard

To date, animal experiments have not yet shown that current cloning technologies are safe enough to try in humans and more insightful and extensive researches should be done over the next few years. However, before any attempt application is employed to humans, it may probably be the most critical step to set up a proper standard or guideline associated with the law

<sup>&</sup>lt;sup>131</sup> See generally, *California Cloning: A dialogue on State Regulation*, in CONVENTIONAL REPORT AT SANTA CLARA UNIVERSITY (October 12, 2001)

for the scientific community that how safe and what degree of risk the human cloning technology must be before it is morally or legally free to explore farther than the past in every aspect. The law may not expect scientists to always reduce risks to zero and introduce a perfect technology in human cloning. Practically a safe standard may be considered reasonable if it is set in the normal range of risk that is acceptable by ordinary people who have personal experience in a similar biomedical technology.<sup>132</sup> Thus, for example, the predicted risk of somatic cell nuclear transfer (SCNT) applied to human cloning for reproductive purpose should not fall above the range of risk that an ordinary person would endure in the assisted reproductive technology (ART).

# **C. Regulatory Framework**

#### 1. Centralized Oversight

Human cloning technologies require to be regulated not only because they raise important moral, social, and legal questions of public concerns, but also because they will inevitably link to several other publicly sensitive applications which are related to human life, health, and reproduction. These include *in vitro* fertilization (IVF), cloning in the form of somatic cell nuclear transfer (SCNT), and germ line modifications. Apparently, these technologies have great potential to substantially affect not only the well-being of the humans, individually or at large,

<sup>&</sup>lt;sup>132</sup> See Gregory E. Pence, *Will Cloning Harm People*? in FLESH OF MY FLESH, THE ETHICS OF CLONING HUMANS 117, 121-122 (Gregory E. Pence eds., Roman & Littlefield Publishers, Inc., 1998)

but also the very meaning of the humanity and human dignity.<sup>133</sup> If their potential applications so weighty that human cloning technology needs a regulatory framework in some extent, then in what form should the regulation be found and at what level should the technology be reviewed?

Generally speaking, there are three basic models for the creation of regulatory framework related to scientific and biomedical practices. They are the market, professional standards, and governmental involvement. However, the prospect of human cloning technology requires more deliberation about social and moral issues than either the market or the science itself can provide. The market is a cold-hearted mechanism substantially ruled by demand and supply. If a society believes some important values such as human rights and human dignity are at stake in this technology, it is not expectable that the market would highlight those values and make a policy decision that is in favor of those morality concerns. Likewise, science may be appropriately motivated in obtaining knowledge and exploring the nature for the public good, but it may still make the policy decision, based on either out of ignorance or self-interest regards, about whether and how to apply the fruits of its effort and endeavor.

Thus, a public oversight body may be most required that will monitor human cloning technology as it is carried out across the whole country. Governmental involvement may be

<sup>&</sup>lt;sup>133</sup> See Cynthia B. Cohen, *Leaps and Boundaries: Expanding Oversight of Human Stem Cell Research*, in THE HUMAN EMBRYONIC STEM CELL DEBATE 219-210 (Suzanne Holland, Karen Lebacqz, and Laurie Zoloth, eds., The MIT Press, 2001)

sometimes subject to most disdain criticism in many fields or matters, but the human cloning technology may be different in kind. Though human cloning will improve the science society and the human race, there is a far greater risk involved in cloning humans. Only government would have the profound authority to competently supervise this technology and review its result. It needs to assure the public that this technology is being undertaken safely and the ethical guidelines are clearly and strictly set up and the foremost among its considerations. Therefore, with the active involvement of government and until this technology has been improved to perfect the cloning procedure as well as an understanding of the moral issues behind human cloning is fully observed, its social and moral implications could be adequately examined.<sup>134</sup>

#### 2. Decentralized Administration

In the human cloning debate, virtually everyone agrees on one point: the need to respect for life and protect the cloned fetes, children, and women from undue risk. Any children produced through cloning, as well as women supplying oocytes and gestating cloned embryos and fetuses, ought to receive the same protections as other human research subjects. Oversight by the government would be essential to providing such protections. Although matters of human cloning is essentially local in nature, that call more or less exclusively for the exercise of decentralized administration of local government, scientific research in publicly sensitive areas

<sup>&</sup>lt;sup>134</sup> See George Annas, *Scientific Discoveries and Cloning: Challenges for Public Policy*, in FLESH OF MY FLESH, THE ETHICS OF CLONING HUMANS 77, 82 (Gregory E. Pence, ed., Bowman & Littlefield Publishers, Inc., 1998)

has to be subject to stringent oversight at the national level in a publicly available manner. In addition, when several or most of the local governments have proscribed some activity related to human cloning they regard as injurious to public health, safety, or morals, to support their proscriptions, the national government should set up centralized legislation with a nationwide framework or standard to effectively oversee the leap and boundary of its relate technologies as a whole. Furthermore, since human cloning has become a subject of international law and only the national government can make treaties or conduct foreign policy for the whole nation, it seems likely that at some point the national government will play a more suitable role to enact legislation on this subject.<sup>135</sup>

## **D.** Sponsorship

## 1. Public Funding

Because laws in many countries, including the United States, preclude public funding for human embryo or fatal research, cell research related to human cloning technology has sprinkled around in a handful of privately funded for-profit biomedical lads and companies. This situation raises questions about the wisdom and correctness of the policy to detain this technology to private, commercial enterprises. In addition, the for-profit mode of the market may eventually

<sup>&</sup>lt;sup>135</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY, AN ETHICAL INQUIRY 183-185 (U.S. Government Printing Office 2002)

influence the research direction and access to its products.<sup>136</sup> If human cloning technology would have great medical potential to the treatment or curing of people from a variety of sickness and illness, what is the proper attitude of public policy to support it and enlighten its possibility of future development? Likewise, if the reasonably anticipated promise of biomedical therapy justifies research on embryonic stem cells, should it be supported with any form of public funds? Would ethical oversight of research be different if the research funding were public or private only?

This is the questions that only the public itself can answer. The study of embryonic and adult stem cells is expected to yield valuable clues about the biology of a number of diseases that plague humanity. More importantly, stem cell research may result in new and better ways to treat cancers, neurological disorders, HIV/AIDS and metabolic disorders such as diabetes. Those diseases have already impacted tens of millions of the people in many countries. Thus, it should be the government's responsibility to do everything possible including the use of public funds to ensure the possibilities of medical potentials related to morally and ethically proper technologies related to the field of human cloning research.

#### 2. Private Venture

<sup>&</sup>lt;sup>136</sup> See Margaret R. McLean, *Stem Cells: Shaping the Future in Public Policy*, in THE HUMAN EMBRYONIC STEM CELL DEBATE 197, 199-200 (Suzanne Holland, Karen Lebacqz, and Laurie Zoloth eds., The MIT Press, 2001)

Prohibitions on the use of public funds may simply force controversial technology into the private sphere, and unilateral or multilateral research bans may also encourage multi-national companies to conduct research in countries that lack restrictive laws. Thus, an unexpected byeffect of stringent regulation restricting the use of public funds in the field of human cloning technology is that research migrates from the public to the private sphere. Because private research receives less oversight and external scrutiny than public research, it can consequently threaten not only the welfare and the fundamental rights of human beings, but also scientific progress and openness, and the quality of the approval process for new biomedical technologies.<sup>137</sup>

Therefore, legislation may not be too rigid to strangle the development of this notorious technology. Nevertheless, based on a neutral and rational policy decision, legislation may still prohibit the government and research facility from using public funds for some specific activities related to human cloning technology, such as performing or attempting to perform human cloning technology only for reproductive purpose, and transferring or receiving the product of human cloning for non-medical purposes, and so forth. On the other hand, since many scientists responsible for the breakthrough biotech in human cloning may have been aided by a variety of

<sup>&</sup>lt;sup>137</sup> See David B. Resnick, Privatized Biomedical Research, Public Fears, and the Hazards of Government Regulation: Lessons from Stem Cell Research, 7.3 HEALTH CARE ANALYSIS 273 (October, 1999)

governmental grants, the genetics knowledge and work should be freely available to the public, and ought not to be exclusively owned by the recipients in private sector.

#### 3. Patenting

Another important element in the management of developing technologies as in human cloning here is patent. A few critics contend that biotech and genetic technologies will become the economic powerhouses of the twenty-first century, and that if private corporations retain control of the use of genes, they will control most economic activities and proceeds. Furthermore, biotech patents will cut down on the exchange of the free exchange of ideas and thus facilitate to concentrate economic powers in private ventures. As a result, patent holders will try their best effort to protect their intellectual properties and be reluctant to freely share their research products. That would hold back the motivation of innovation in the scientific community and be harm to all of the society as a whole in the long run.<sup>138</sup> For that reason, legislation should pay more caution in the questions of patenting human cloning technologies because those would not only substantially influence the well-being of people, but also deeply involve the philosophic or moral considerations about whether a life should be patented, just like any other newly-invented commodity.

<sup>&</sup>lt;sup>138</sup> See PETER SHANKS, HUMAN GENETIC ENGINEERING 288-290 (Nation Books, 2005)

Even if any part of the procedure of human cloning technology can be a subject of intellectual property protection, Article 4 of Universal Declaration on the Human Genome and Human Rights (UDHGHR) stipulates that "[T]he human genome in its natural state shall not give rise to financial gains." Similarly, Article 21 of the European Convention on Human Rights and Biomedicine (ECHRB) also mentions that "[T]he human body and its parts shall not, as such, give rise to financial gains." While patenting may provide an incentive for scientific, technological, or pharmaceutical research and ensure the disclosure of the outcomes of such research to the world at large, premature and excessively rapid growth of intellectual property protection will impede the flourishing of free and uninhibited research. Therefore, it is essential to find approaches as harmony as possible to address such concerns and promote international cooperation to support a commonly-acceptable concept of benefit sharing with equity.<sup>139</sup>

## IV. Conclusion

The advent of human cloning technology—or somatic cell nuclear transfer (SCNT)—has thrust policymakers into the scientific world of genetics research. The debate over ethical and legal issues surrounding the use of cloning for reproductive purposes has led to accompanying

<sup>&</sup>lt;sup>139</sup> See African Union, Issue of Human Cloning within the Overall Context of a Bioethics Programme: Priorities and Perspectives for Africa, 12/8/2004, available at http://african-union-news.newslib.com/story/1589-1106643/

public discussion of stem cell research. While this discussion has alerted people of the growing role of serious issues in human cloning, it has also generated much uncertainty in this field. Policymakers can help to guide the learning process and ensure the formulation of sound public policy for cloning technology with a throughout understanding of the potential uses, benefits and risks of reproductive and biomedical cloning technologies.

Concerns about human cloning run sufficiently deep in many aspects. Even those who would make money on the procedure have come out against it. Dr. Ian Walmut, the scientist whose team cloned Dolly the sheep, might benefit financially if humans were cloned because his group holds a patent on a cloning process. Similarly, the Biotechnology Industry Organization (BIO), a U.S. trade association of biotechnology companies, opposes human cloning for reproductive purpose. Numerous entities have called for an enforceable ban on species-altering interventions. Since cloning for the replication of human individuals is ethically unacceptable to most countries in the world and morally contrary to human dignity and integrity, the World Health Organization (WHO) urged member states at its fifty-first World Health Assembly on May 16, 1998 "[T]o foster continued and informed debates on these issues and take appropriate steps, including legal and juridical measures, to prohibit cloning for the purpose of replication human individuals."<sup>140</sup>

It is also noted that the currently available information from animal studies involving cloning by somatic cell nuclear transfer indicates that this would be an unsafe procedure to the human. Developments in cloning would not only have unprecedented ethical implications but also raise serious matters for concern in terms of safety of the individual and subsequent generations of human beings. Thus, the future legal status of human cloning technology, either for reproductive or research purpose, needs to be earnestly resolved in an informed and timely manner based on proper policy-making decisions at national or international level.

<sup>&</sup>lt;sup>140</sup> See Lynn P. Freedman, *Censorship and Manlpulation of Family Planning Information: An Issue on Human Rights and Women's Health*, in PERSPECTIVES ON HEALTH AND HUMAN RIGHTS 145, 148 (Sofia Gruskin, Michael A. Grodin, George J. Annas eds., Routledge, 1999)
## <u>Chapter 4</u>

# <u>Safeguard Rights and Liberties Essential to the Future of</u> <u>Humanity in the Cloning Age</u>

## I. Introduction

Since the birth of "Dolly the sheep" in July 1996, cloning technology via the nuclear transfer of differentiated cells has been successfully expanded to numerous and varied animal species, including pigs, mice, goats, cows, and many other mammals. It seems that applying cloning techniques to humans is only a matter of time. Indeed, in late November 2001, researchers at Massachusetts-based Advanced Cell Technology (ACT) in the United States announced that they had already gone past the seven-day stage in stem cell research in animals. They had taken cloned cow embryos past the blastocyst stage, taken tissue from the more developed cow fetus, and re-implanted it back into the donor animal. The scientists also claimed that they had used the same somatic cell nuclear transfer (SCNT) technology to create embryos in humans. Realizing the inevitability of successful human cloning of any kind in the nearest future, numerous countries and regions in the international community, commonly based on the so-called slippery slope theory, have promptly enacted prophylactic bans on human cloning and its related techniques.<sup>141</sup>

Slippery slope theory presumes that everything will go forward to a worse direction. Once a person has done an ethically acceptable act x which may be good, he or she will inevitably do another ethically unacceptable act y which will be bad. There may be two reasons which make the acts slip from x to y. First, it may be difficult for the people to clearly distinguish between x and y. Second, a societal circumstance which permits y is created due to the existence of x. Consequently there are three suspicions that underline slippery slope arguments against human cloning technology. First, it is doubted that this new technology could be put to some extremely undesirable uses which would be drastically contrary to moral or religious imperatives. Second, it is highly possible that someone would make use of this new technology to those undesirable ends which could be seriously harmed to humans. Third, the capacity of any existing society to launch effective control and regulation to prevent these undesirable uses of this new technology is uncertain.

If scientists are permitted to conduct research into cloning human embryos in order to either reproduce child for people suffering from emotional distress or cultivate replacement

<sup>&</sup>lt;sup>141</sup> See Charles Krauthammer, *Crossing Lines*, in THE HUMAN CLONING DEBATE 79, 86 (Glenn McGee, Arthur Caplan eds., Berkeley Hills Books, 4<sup>th</sup> ed., 2004)

tissue for people suffering from degenerative diseases, the society may eventually break the promise to respect and protect for human life and dignity and will inevitably face an unacceptable charge of infringement and violation of essential rights and liberties which are duly recognized or ensured by most civilized countries and the international community as well. Although the risk that this technique could be excessively abused is not an adequate justification for banning and the slippery slope theory has yet been fully concurred among experts and scholars, the assumption that our ability to control inappropriate applications of human cloning technology should still be gravely evaluated. Especially in this new bioengineering era, ethical and moral considerations always call out for thoughtful protections of impinged rights and liberties of people through plausible regulations and proper policies against the motiveless misuse or neglectful use of novel genetic technologies as human cloning technology here.

This chapter will observe those rights and liberties that may be most vulnerable to be challenged in human cloning episode but encompass moral essence to life, freedom, and dignity of the human. In addition to the rights and liberties with personal nature that deserve individual protections from unwarranted infringements, other rights with collective nature may also be explored if their realizations have to rely on the governmental support of better social, economic, or cultural environments as a whole.

## II. Substantive Justice

## A. Procreative Liberty

General speaking, procreative liberty is the freedom of individuals to have control over their capability to reproduce, with the assurance that their acts are still within the limits of safety, ethics and conscientiousness. Consequently, procreative liberty can be considered a personal freedom to decide, under the framework of common goods, whether or not he or she would like to have offspring. It is a deeply acknowledged moral value and pervades many of social practices in the international community.<sup>142</sup> In addition, the desire to reproduce is also an important instant. It connects people with nature and the next generation, gives them a sense of immorality, and enables them to realize the fantasy to rear and parent children of their own. Thus, depriving a person of the ability or opportunity to reproduce a child may be deemed a major burden and substantial infringement to his or her freedom and should not occur unless the government has a compelling state interest to justify this intrusion and with informed and voluntary consent or decision freely made by the suffered.<sup>143</sup>

#### 1. Liberal Perspective

<sup>&</sup>lt;sup>142</sup> See JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 22-42 (Princeton Press, 1994)

<sup>&</sup>lt;sup>143</sup> See John A. Robertson, *Cloning As A Reproductive Right*, in THE HUMAN CLONING DEBATE 177, 179 (Glenn McGee, Arthur Caplan eds., Berkeley Hills Books, 4<sup>th</sup> ed., 2004)

The liberal perspective sets cloning in the framework of rights, freedoms and personal empowerment. Cloning is just a new option for exercising an individual's liberty to reproduce or to have the kind of child that he or she would like to have. The question of whether cloning is part of procreative liberty may be serious only if non-coital, assisted reproduction could be considered part of that liberty. A strong argument exists that the moral right to reproduce does include the right to use non-coital or assisted means of reproduction. Infertile couples have the same interests in reproducing as coitally fertile couples and the same abilities to rear children. It thus follows that married couples and single persons as well have moral rights to use non-coital assisted reproductive techniques, such as *in vitro* fertilization (IVF) and artificial insemination with a spouse or partner's sperm, to beget biologically related offspring for rearing.

It should also follow that the infertile couple would have the right to use gamete donors, gestational surrogates, and even embryo donors if necessary. Although third-party collaborative reproduction procedures do not replicate exactly the genes, gestation, and rearing unity that ordinarily arises in coital reproduction, they come very close and should be treated accordingly. Each of these procedures, with varying degrees of closeness, enables the couple to

have or rear children biologically related to at least one of them, so that their procreative liberty may be fully realized.<sup>144</sup>

#### 2. Eugenics

For those who hold liberal outlook of human cloning technology believe that the only moral restraints on cloning are adequately informed consent and the avoidance of bodily harm to any related persons.<sup>145</sup> However, unlike the various forms of assisted reproduction, cloning deserves more concerns not only because it reproduces children through non-natural ways, but also it involves genetic selection for the resulting child. Notoriously, cloning techniques which create human embryos cloned from desirable genotypes have great potential to manipulatively select the entire nuclear genome for a prospect child. Therefore, since cloning may serve the ends of individualized enhancement either by avoiding the genetic defects that may arise when human reproduction is left to chance or by preserving and perpetuating outstanding genetic traits, a further enhanced cloning through more precise genetic engineering may lead to facilitate eugenic program designed to improve the human species or prevent a severe deformation of the future child.

<sup>&</sup>lt;sup>144</sup> See John A. Robertson, Liberty, Identity, and Human Cloning, 76 Tex. L. Rev. 1371 (1998)

<sup>&</sup>lt;sup>145</sup>See Leon Kass, *The Wisdom of Repugnance: Why We Should Ban the Cloning of Humans*, in THE HUMAN CLONING DEBATE 137, 148-149 (Glenn McGee, Arthur Caplan eds., Berkeley Hills Books, 4<sup>th</sup> ed., 2004)

The term of "eugenics" generally refers to attempts to improve the genetic constitution of a particular political community or of the human race through general policies such as population control, forced sterilization, directed mating, or the like.<sup>146</sup> In the early decades of the twentieth century, this so-called "pseudoscience" became popular and was an attempt to breed a "better" human race by encouraging those with "good" genes to have children, while discouraging those with "bad" genes from having children. Eugenics has a bad reputation ever since majorly because Nazi Germany used this theory to mandate the sterilization of persons who suffered from what were believed at the time to be heritable disabilities, including feeblemindedness, schizophrenia, epilepsy, blindness, alcohol addiction, and physical deformities.

Given this dreadful history, many people inevitably associate eugenics with horrified coercion, involuntary sterilization, and even systemized execution initiated by the government.<sup>147</sup> Even if privately-sponsored free-market eugenic projects occurred in modern democratic societies in which the government might not be involved in cloning practices would not carry with dark implications of state despotism or political control of the gene pool that characterized earlier eugenic proposals and the racist eugenic programs of the twentieth century, genetic

<sup>&</sup>lt;sup>146</sup> See THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 107 (The U.S. Government Printing Office, July 2002)

<sup>&</sup>lt;sup>147</sup> See KERRY LYNN MACINTOSH, ILLEGAL BEINGS: HUMAN CLONING AND THE LAW 39-40 (Cambridge University Press, 2005)

engineering in combination with cloning could still have effect to substantially reduce the genetic diversity among humans and would eventually change the nature of humanity.

Furthermore, while the prospect of genetically redesigned people challenges humanity as a whole, it particularly threatens groups that historically have been disempowered such as indigenous people and women. Because human germline engineering and cloning are so closely tied to the realization of people's reproductive right, and the threat of eugenics is inherent in cloning technologies that allow individuals to try to modify inherited characteristics so as to give preference to specific ones, the possibility of new eugenic projects accomplished through human cloning technology and proposed today for either personal, societal, economic or any other purposes should still deserve more serious concerns.

#### **B.** Right to Privacy

Although it is undoubtedly true that a person's appearance, characteristics and abilities are not determined by their DNA, there are a few medical conditions that are caused by genetic abnormalities. If someone with the gene that causes Huntington's disease were to be cloned, the clone would also have the relevant gene, and would therefore develop the disease. Since the DNA source's knowledge of their genetic make-up translates into identical knowledge about the clone, significant questions about genetic privacy and confidentiality may arise. By the time human reproductive cloning becomes safe enough to attempt in humans, this problem is likely to have been aggravated by advances in the breadth and accuracy of genetic testing. In the realm of health care in which human cloning may find its ground to grow, the advent of genetic testing has been accompanied by great concerns about the unauthorized dissemination and improper use of this genetic information.

#### 1. Genetic Privacy

Science is only beginning to decipher the relationships between genes and physiology and behavior of humans. Researchers have identified a gene or two with connections to a number of complex behavioral traits nit know little about the mechanisms or how many genes are involved. Once the sequence of the human genome has fully completed, a bundle of personal information will of course be inevitably released for many reasons without knowledge or authorization. For example, the genetic research highlights the importance of attention to the intrinsic harms associated with violations of genetic privacy. Likewise, the genetic information obtained in either reproductive or biomedical cloning procedures may also encounter similar situation as those in any realm of life science. Especially when large numbers of people want something than regulators cannot monitor and that small laboratories in any country can provide, then those people will obtain it. Should the genetic information be considered in the sphere of personal privacy and be strictly safeguarded by the law?

Right to privacy would appear to be a relatively simple concept, i.e., leave me alone." Although privacy in health care system has been vigorously defended but still inadequately justified. This is partly because privacy is a complex concept with no universally accepted definition. As described by Anita Allen in 《Genetic Secrets》, published by Yale University Press in 1997, the concept of privacy in the health care may be classified into four distinct dimensions: "Physical privacy relates to the notion of seclusion, solitude, and freedom from unwanted and unwarranted contact with other people; Informational privacy is expressed in practices that impose limits on the accessibility of personal information revealed to another and what we think as confidentiality; Decisional privacy means that individuals ought to be able to make certain personal decisions free from intrusions or coercion by third parties; and Proprietary privacy asserts the individual's right with respect to their stored biological samples and information obtained from these."<sup>148</sup> All definitions of privacy acknowledge that it is an essential value necessary to individuality and the proper development of personality. Accordingly, the law guaranteeing the individual right to privacy should fully applied to the field of genetic information here.

#### 2. Confidentiality

<sup>&</sup>lt;sup>148</sup> See Jeroo Kotval, *Genetic Privacy in the Health Care System*, in RIGHTS AND LIBERTIES IN THE BIOTECH AGE 153, 154 (Sheldon Krimsky, Peter Shorett eds., Rowman & Littlefield Publisher, Inc., 2005)

On the other hand, confidentiality may be conceptualized as the communication of private personal information from one person to another when it is expected that the recipient of the information, such as a health professional, will not ordinarily disclose the information to a third person.<sup>149</sup> It ensures that the patient has control over his or her privacy by allowing the patient to determine what information should be revealed, to whom, when, and how.<sup>150</sup>

Confidentiality issues already arise between family members who undergo genetic tests, and these are obviously especially pronounced for identical twins where the discovery of a genetic abnormality in one twin is tantamount to a positive diagnosis for the other one. However, the existence of confidentiality problems is not a sufficient reason to prevent cloning. Rather, traditional means of ensuring confidentiality do not apply to genetic data and that additional safeguards are needed to protect patients from potential abuses. If human reproductive cloning were to become possible, rules that already exist in relation to the cross-referencing of information from different family members would still need to contain the special implications of a parent and child with a shared genotype.

In addition, confidentiality is also important in genetic testing. The confidentiality of genetic information may need to be guarded even more stringently than in the ordinary case.

<sup>&</sup>lt;sup>149</sup> See William J. Winslade, *Confidentiality*, in ENCYCLOPEDIA OF BIOETHICS 452 (Warren T. Reich ed., Simon and Schuster Macmillan, 1995)

<sup>&</sup>lt;sup>150</sup> See Jeroo Kotval, supra, note 148, at 155

Genetic tests give an assessment of an individual's inherent risk for disease and disability. This predictive power makes genetic testing particularly liable for misuse. A fear of genetic discrimination may also be incurred if those tests associate with the selection or manipulation of embryos. Employers and insurance companies have always been known to deny individuals essential health care or employment based on knowledge of genetic disposition. This type of discrimination can be socially debilitating and have severe socio-economic consequences. It is important, therefore, to ensure the confidentiality of test results, and to establish legislation permitting only selective access to this information.<sup>151</sup>

However, genetic information may have important implications not only for the one who is tested, but also for her relatives. Respecting a patient's confidentiality by not disclosing the results of a genetic test to third parties could therefore conflict with the well-being of family members, who could benefit from this knowledge. Thus, finding the balance between the patient's privacy and confidentiality of her genetic information, and what is in the best interests of family members, is an ongoing ethical and social challenge in the international community.

#### C. Right to Health

<sup>&</sup>lt;sup>151</sup> See World Health Organization (WHO), Genetic Testing, at http://www.who.int/genomics/elsi/gentesting/en/

People have the right to the highest attainable standard of physical and mental health, without discrimination of any kind. Enjoyment of the right to health is vital to all aspects of a person's life and well-being, and is crucial to the realization of many other fundamental rights and freedoms. Right to health is probably the most directly concerned and the most ambiguous. Those who oppose human genetic manipulation involved in cloning procedure believe that it threatens human well-being and therefore violated the right to health. To the contrast, those who support new eugenics accomplished through human cloning consider such technology as potentially enhancing human well-being and therefore contributing to the realization of the right to health.<sup>152</sup>

#### 1. Modern Concepts

Modern concepts of health derive from two related but quite different disciples: medicine and public health. Medicine generally focuses on the health of an individual, while public health emphasizes the health of populations. Furthermore, individual health has been the concern of medical and other health care services, generally in the context of physical and mental illness and disability. On the other hand, public health has been described as ensuring the conditions in which people can be healthy. Thus, public health has a distinct health-promoting goal and

<sup>&</sup>lt;sup>152</sup> See Stephen P. Marks, Human Rights Assumptions of Restrictive and Permissive Approaches to Human Reproductive Cloning, 6.1 HEALTH AND HUMAN RIGHTS 81, 92-93 (2002)

emphasizes prevention of disease, disability, and premature death.<sup>153</sup> Preamble to the Constitution of the World Health Organization (WHO), as adopted by the International Health Conference, New York on 22 June 1946, states that "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."<sup>154</sup> Through this definition, WHO has helped to move health thinking beyond a limited, biomedical, and pathology-based perspective to the more positive domain of "well-being."<sup>155</sup>

#### 2. Medical Promises

Look back to the medical promise of therapeutic and research cloning which are primarily designed for curing physical and mental diseases suffered by the patients and other related persons. Many people suffer from chronic debilitating diseases and disabilities, including, among others, juvenile diabetes, Parkinson's disease, Alzheimer's disease, spinal cord injuries, heart disease, and amyotrophic lateral sclerosis. These terrible diseases shorten life, limit activity, and cause great suffering both for the afflicted and their families. Even more, the likelihood of premature death can shadow the life of the patient and the patient's family even

<sup>&</sup>lt;sup>153</sup> See Jonathan M. Mann, Lawrence Gostin, Sofia Gruskin, Troyen Brennan, Zita Laarini, and Harvey Fineberg, *Health and Human Rights*, in HEALTH AND HUMAN RIGHTS: A READER 7, 8 (Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, George J. Annas eds., Routledge, 1999)

<sup>&</sup>lt;sup>154</sup> See Official Records of the World Health Organization, n.2, p.100

<sup>&</sup>lt;sup>155</sup> See Mann et al., supra, note 153, at 8

before it arrives, and its advent can take away and devastate families, tear hopes, and cast a chill on the lives of survivors.<sup>156</sup>

Human cloning initiated for research and therapy purposes may successfully lift their burden and effectively promote the well-being of each affected persons. This technology may offer unique ways of research and investigation to improve understanding of several of human disease. It may also potentially useful for assessing and developing chemical or pharmaceutical treatments for the diseases in question. In addition, some animal studies suggest that tissues derived from embryonic stem cells can, if injected under certain conditions such as rejectionproof from normal immunological function, populate disease-stricken areas and differentiate so as to compensate for the loss of function caused by the diseased tissue and to help patients fight disease and restore health. Cloning technologies could also be combined with precise genetic manipulation to devise genetic treatments from genetic disease.<sup>157</sup> This combined approach to gene therapy has shown early promise in one attempt to correct a genetic abnormality in the immune system of mice.<sup>158</sup>

In February 2004, South Korean scientists alleged the creation of a stem cell line from a cloned human embryo. According to their stated report, scientists enucleated two hundred and

<sup>&</sup>lt;sup>156</sup> See The President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry 129-130 (The U.S. Government Printing Office, July 2002)

<sup>&</sup>lt;sup>157</sup> Id., at 131-133

<sup>&</sup>lt;sup>158</sup> See Rideout III, W. M., et al., Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy, 109 CELL 17, 27 (2002)

forty-two oocytes from sixteen donors into which they transferred the DNA of ovarian cells from the same donors. Thirty embryos reached the blastocyst stage; from these, the scientists extracted the inner cell mass for the cultivation of stem cell lines, one of which was successfully established. Six months later the U.K. Human Fertilsation and Embryology Authority (HFEA) granted the first license in Europe to allow researchers to use SCNT cloning for embryonic stem cell research. Scientists who are interested in such research look ahead to the day when they believe that embryonic stem (ES) cells will be used to assist drug development and evaluation, for diagnostic purposes, and to create cells and tissues for transplantation.

For the latter, if the stem cells used in transplantation were derived from embryos cloned from the patient needing the transplant, they might be less subject to rejection than cells, tissues or organs from another person, since the DNA in the cloned cells would be nearly identical to the patient's own. The questions of whether human embryonic stem cells, opposed to stem cells from adult tissues, hold unique therapeutic promise, and, if so, whether the creation of cloned embryos as a source of stem cells would include in the moral value of people's right to health are critical matters of ongoing debate in scientific spheres.<sup>159</sup>

## **D.** Right to an Open Future

<sup>&</sup>lt;sup>159</sup> See WORLD HEALTH ORGANIZATION (WHO), A DOZEN QUESTIONS (AND ANSWERS) ON HUMAN CLONING, available at http://www.who.int/ethics/topics/cloning/en/

Some scholars have argued that the human use of reproductive cloning and genetic engineering should be prohibited because these biotechnologies undermine the autonomy of the resulting child. Similarly, in many countries there are laws prohibiting the use of cloning and genetic engineering as methods of human reproduction. Commentators agree that coercive and state-directed uses of these reproductive technologies should be avoided. However, the controversy is focus on whether would-be parents should be allowed to use such technologies as one of variety of tools for satisfying their reproductive desires.<sup>160</sup> Some people object to the creation of a new human being by cloning an already existing human being because they think that the clone would be a replica of the original person, alike in all respects, and hence the child is not a unique individual whatsoever.

#### 1. Future of the Cloned

Normally, each individual develops his or her personality and becomes a self by making choices with free will. However, a cloned human being would know the choices that were made by the person whose genome he or she shared. The clone would know a great deal about him or herself and his or her future. He or she would know what he or she would look like as an adult, the disease to which he or she would be prone, the talents he or she would have, and so forth.

<sup>&</sup>lt;sup>160</sup> See M. Mameli, Reproductive Cloning, Genetic Engineering and the Autonomy of the Child: the Moral Agent and the Open Future, 33 J. MED. ETHICS 87 (2006)

Thus, he or she would be unable to create and become his or her own life.<sup>161</sup> The fear caused by reproductive cloning technology is that the future of the cloned individual would be predetermined, narrowing that the child's choices when he or she grows up. Consequently, the child's right to an open future would be seriously infringed.<sup>162</sup>

The term of the right to an open future is not easy to be defined as a simple meaning. Originally the term refers to parent's environmental rather than genetic choices.<sup>163</sup> Buchanan *et al* suggest that the best way to make sense of Feinberg's notion is as follows:

[T]he idea is that parents have a responsibility to help their children during their growth to adulthood to develop capacities for practical judgment and autonomous choice, and to develop as well at least a reasonable range of the skills and capacities necessary to provide them the choice of a reasonable array of different life plans available to members of their society. [...] In this view, it would be wrong for parents to close off most opportunities that would otherwise be available to their children in order to impose their own particular conception of the good life.<sup>164</sup>

According to Buchanan et al, the principle that parents should not be allowed to make

choices resulting in their children not having a reasonable array of life plans from which to

<sup>&</sup>lt;sup>161</sup> See Bonnie Steinbock, Cloning Human Beings: Sorting through the Ethical Issues, in HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY 68, 71-72 (Barbara Mackinnon ed., University of Illinois Press, 2000)

<sup>&</sup>lt;sup>162</sup> See Dena S. Davis, Genetic Dilemmas and the Child's Right to an Open Future, 28 RUTGERS L. J. 549 (1996)

<sup>&</sup>lt;sup>163</sup> See Joel Feinberg, *The Child's Right to an Open Future*, in FREEDOM AND FULFILLMENT 76-97 (Princeton University Press, 1992)

<sup>&</sup>lt;sup>164</sup> See Allen E. Buchanan, Dan W. BROCK, NORMAN DANIELS, DANIEL WIKLER, FROM CHANCE TO CHOICE: GENETICS AND JUSTICE 170 (Cambridge University Press, 2000)

choose should be applied to both environmental and genetic choices. Thus, a genetic intervention that makes a child particularly fit to pursue a career as, say, a pianist but unfit to pursue any other available career, would be illegitimate, especially in contemporary societies where a relatively large range of choices is usually available to most people. Genetic interventions that make children fit for only a restricted range of ways of life violate the right to an open future and should thereby be banned.

#### 2. Genetic Choices

However, many issues still remain unsolved. Many would-be parents are likely to want to use genetic engineering to increase the probability that their children develop traits, such as high intelligence, which would make the children more likely to succeed in a whole range of different life plans. Such genetic choices would in general enlarge rather than reduce the array of life plans available to the future child. Would this situation violate the child's right to an open future? Furthermore, only genes alone cannot determine what we are or will be. Each individual is the result of a complex interaction between his or her genes and the environment within which they develop. As the words in the NBAC Report, "[I]ndeed, the great lesson of modern molecular genetics is the profound complexity of both gene-gene interactions and geneenvironment interaction in the determination of whether a specific trait or characteristic is expressed. In other words, there will never be another you."<sup>165</sup> Accordingly, genetic manipulation used in human reproductive cloning may artificially select the genome traits for the cloned child, but his or her future may remain quiet open depends at least as much on surrounding environmental factors as on his or her genetic inheritance.

## **III.** Procedural Justice

## A. Right to Life

Right to life is a phrase that describes the belief that a human being has an essential right to live, particularly that a human being has the right not to be killed by another human being. Generally, the concept of a right to life is central to debates on the issues of capital punishment, euthanasia, self-defense, abortion and war. Article 3 of the United Nations Universal Declaration of Human Rights (UDHR) is dedicated to the right to life as is article 6 of the International Covenant on Civil and Political Rights (ICCPR), making it a legally enforceable right in every member state of the United Nations, state: "Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."

<sup>&</sup>lt;sup>165</sup> See National Bioethics Advisory Commission (NBAC), CLONING HUMAN BEINGS, in REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 32 (1997)

#### 1. Pro-life Advocacy

Pro-life is a term representing a variety of perspectives and activist movements in bioethics. It can be used to indicate opposition to practices such as euthanasia, human cloning, research involving human embryonic stem cells, and the death penalty, but most commonly to abortion, and support for fetal rights. The term describes the political and ethical view which maintains that all human beings have the right to life, and that this includes fetuses and embryos. Pro-life advocates who support this concept argue that human fetuses (as well as embryos and zygotes) are unborn human beings who have the same fundamental right to life as that of a human being after birth. Generally those who identify themselves as "right to life" are strongly opposed to abortion; many oppose euthanasia, and some oppose embryonic stem cell research. However, some notable right-to-life figures, such as U.S. Senate Orrin Hatch, do support stemcell research for advanced therapy technology.<sup>166</sup> The moral status of embryos still remains undecided.

*Davis v. Davis* was a case decided by the Supreme Court of Tennessee in the United States with issues regarding the legal position of the embryos.<sup>167</sup> In *Davis*, Mr. and Ms. Davis

<sup>&</sup>lt;sup>166</sup> Sen. Orrin G. Hatch (R-Utah) urged President Bush to advance the promising field of ethical embryonic stem cell research by allowing federal funding to support scientists using stem cells derived from frozen embryos that are discarded each year. He defended: "A critical part of being pro-life is to support measures that help the living," he said. "And this research enhances, not diminishes, human life. Regardless of the president's actions, we intend to keep pushing this research forward." See Jennifer Talhelm, *Hatch Defends Stem Cell Research*, in DAILY HERALD NEWS, 18 July 2006, at http://www.heraldextra.com/news/article\_922f18b1-1117-5e14-b33e-0d8203f70ab0.html

<sup>&</sup>lt;sup>167</sup> See Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992)

were involved *in vitro* fertilization (IVF) and then, post-divorce, dispute the disposition of their embryos. Mr. Davis wanted the embryos destroyed, and Ms. Davis wanted them donated to an infertile and childless couple. The lower court decided that the embryos were joint property and should be equally divided between Mr. and Ms. Davis. However, the Tennessee Supreme Court concluded that the embryos were neither legal persons nor a form of property. It held that the embryos occupy a special category that entitled them to special respect because of their potential for human life. The decision making authority concerning disposition of the embryos was only to the extent within the scope of policy set by law.<sup>168</sup>

Breaking through the middle line drawn by the Tennessee Supreme Court over the fate of cryopreserved embryos, those who oppose human cloning insist that this technology is an inherent violation of human dignity. As with abortion and assisted reproductive technologies, such as *in vitro* fertilization (IVF), human cloning research denies one of the most fundamental of human rights, e.g., the right to life. The research process inevitably requires scientists to destroy and discard their failed experiments, for example, it took two hundred and seventy-seven attempts at cell manipulation and twenty-nine embryo implants before the sheep Dolly was produced. Even more, cloning would further violate human dignity by denying the intrinsic value of each human life, thereby viewing human beings as products or commodities. Cloning

<sup>&</sup>lt;sup>168</sup> Id., at 590

could not possibly respect for the intrinsic value of the person created, because a cloned person will not be created simply for their value as a person. There will always be an intended and specific utility attached to a cloned person because he or she was created with a particular genetic make-up for some purpose. Any action taken to create or destroy human being, mainly based on their genetic qualities and their intrinsic value, would be deemed lack of respect for life and thus violate their right of life.

#### 2. Embryo's Right to Life

According to the prevalent legal system in certain countries, embryo may be treated as an individual and is entitled to the right to life. The embryo's right to life begins with the right to be born. However, the right of an unborn child is a glaring question mark before the legislators and regulators. *Vo v. France* which was a case decided by the European Human Rights Court (EURC) brought into the forefront the issue regarding the rights of a fetus or an unborn child.<sup>169</sup> In *Vo v. France*, the Grand Chamber of seventeen judges of the ECHR evaded the controversial issue of whether a fetus is a person for the purposes of article 2 of the European Convention on Human Rights (ECHR), which states: "[E]very one's right to life shall be protected by law."<sup>170</sup> The troubling conclusion to be drawn from *Vo* is that there is no clear resolution to the status of

<sup>&</sup>lt;sup>169</sup> See Vo v. France, No. 53924/00, ¶ 19 (Eur. Ct. H.R. July 8, 2004) (citation omitted), also available at http://www.echr.coe.int

<sup>&</sup>lt;sup>170</sup> See European Convention for the Protection of Human Rights and Fundamental Freedoms opened for signature Nov. 4, 1950, Art. 2, 213 U.N.T.S. 221 (entered into force on 3 September 1953)

the fetus. The Court chose the easier path of holding that even if article 2 applied, France had not violated its provisions.<sup>171</sup>

As a result, this term "everyone" still remain unclear and is always the main issue of many similar situations including cloned embryos created for stem cell research and therapeutic purpose here. Should we treat those human embryos existing in the laboratory one of "everyone" or at least a "being" of human life? Could a human blastocyst which possesses differential powers to become a mature human being deserve to be regarded only as a thing or mass without human life or dignity? Should such a blastocyst be endowed with the right to life? These questions need to be cleverly resolved by our community. As sooner as better, the proponents of producing human embryos for research purposes should provide a reasonable standard to legitimate the new endeavors on which they want society to recognize and realize. Any recommended practices which contradict legitimating attitude should be revoked. For the long run, the scientists and related scholars ought to offer sufficient grounds for public confidence that they can effectively safeguard against any likely abuse of life, either before or

<sup>&</sup>lt;sup>171</sup> See Tanya Goldman, Vo v. France And Fetal Rights: The Decision Not To Decide, 18 HARVARD HUMAN RIGHTS JOURNAL 277 (Spring 2005)

after birth.<sup>172</sup> The regulatory responses in Ireland provide a practical inspiration for many countries if their policy of protecting embryo's right to life is still uncertain.

The Eighth Amendment to the Irish Constitution (which forms Article 40.3.3) states "The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right." While this provision does not mention cloning, it has been taken to protect *in vitro* embryos and thereby have the effect of prohibiting any kind of human cloning, either for reproductive or therapeutic purposes.<sup>173</sup> In addition, doctors must comply with the guidance of the Medical Council, as this body has the power to remove their license to practice in Ireland. The Medical Council's guidelines declare that " [T]he creation of new forms of life for experimental purposes or the deliberate and intentional destruction of human life already formed is professional misconduct." Also, it limits the manipulation of sperm or eggs to the "improvement of health" and adds that "if the intention is...the creation of embryos for experimental purposes, it would be professional misconduct."<sup>174</sup> Thus, the absence of anticloning legislation in Ireland does not render all things permissible. The national policy towards

<sup>&</sup>lt;sup>172</sup> See James Keenan, Casuistry, Virtue, and the Slippery Slope: Major Problems with Producing Human Embryonic Life for Research Purposes, in CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH 67 (Paul Lauritzen, ed., Oxford University Press, 2001)

<sup>&</sup>lt;sup>173</sup> See Shaun D. Pattinson, Timothy Caulfield, Variations and Voids: the Regulation of Human Cloning around the World, 5 BMC MEDICAL ETHICS 9 (2004), also available at http://www.biomedcentral.com/1472-6939/5/9

<sup>&</sup>lt;sup>174</sup> See Medical Council: A Guide to Ethical Conduct and Behaviour, 26.1-26.2 (1998)

the protection of embryo's right to life in human cloning process has been clearly introduced in its related regulatory scheme.

#### **B.** Autonomy for Self-Determination

Respect for persons has a number of aspects. The central concern is respect for individual as well as individual decision-making. These ideas are related to a range of ethical concerns, including recognition of, and respect for, the inherent value of persons, recognition of the value of self-determination to the wellbeing, happiness and moral development of individuals, and respect, within a liberal democracy, for individual freedom, including freedom of choice. Personal autonomy has been variously characterized as the capacity for individual self-determination, as freedom from coercion, undue influence and external restraint in decision-making, and as the capacity for deciding and acting in accordance with one's own values. Political autonomy is the idea of a people's self governance and self-determination and is contrasted with political subordination and domination.<sup>175</sup> In addition, personal autonomy should extend beyond mere free, informed choice, however, to include recognition of the

<sup>&</sup>lt;sup>175</sup> See NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL (NHMRC) OF AUSTRALIAN GOVERNMENT, NATIONAL STATEMENT ON NATIONAL CONDUCT IN HUMAN RESEARCH ON 2007, 1.2, 1.4 & COMMENTARY PREAMBLE, available at http://www.nhmrc.gov.au/publications/hrecbook/02\_ethics/40.htm

contexts of personal choice and the development of the capacity for personal autonomy.<sup>176</sup> As a result, people should no doubt be free in their reproductive decisions. The State or international organizations do not have the power to arbitrarily interfere with reproductive autonomy of any person unless informed consent provided otherwise.

#### 1. Informed Consent

The idea of informed consent grows out of the principle of autonomy and is a major contribution of modern bioethics. If the victims of Nazi experiments and of the Tuskegee study had been fully informed and free to participate or not, they would not have been suffered. The major benefit of autonomy is that what is the best for each of us depends on our individual values. Each of us generally knows more about our own values than others know about them. Thus, even if others tried to make the best decision for us, they would usually not do so as well as we would do by ourselves.<sup>177</sup> Based on the deontological principles such as autonomy and respect for persons, the requirement for obtaining consent prior to further treatments should apply to both reproductive and research human cloning processes.

In order to assist cloning participants to make an informed consent, the context of consent document should include, but not limit to, the natures, steps, risks, costs, and expectations of all

<sup>&</sup>lt;sup>176</sup> See S. Dodds, *Choice and Control in Bioethics*, in RELATIONAL AUTONOMY IN CONTEXT: FEMINIST PERSPECTIVES ON AUTONOMY, AGENCY AND THE SOCIAL SELF 213-235 (Catriona Mackenzie, Natalie Stoljar eds., Oxford University Press, 2000)

<sup>&</sup>lt;sup>177</sup> See JONATHAN BARON, AGAINST BIOETHICS, 97, 106-109 (The MIT Press, 2006)

the procedures to be performed on the participants. The likelihood of success and failure of the cloning process and the use, storage, transfer, releasing, disposition, donation, or ultimate abandon or destroying of the resulting embryos should also be described in this consent document. The purpose of informed consent is to provide the cloning participants with sufficient information with which to make an intelligent choice regarding procedures they are going to go through and tolerate. For example, before commencing the somatic cell nuclear transfer (SCNT) cloning process, the participants should be required to execute informed consent documents and undersigned by the SCNT facility for expressing its responsibility in this event. The forms should be detailed and composed in language that is easily understood by the participants.

It is noted that any child created through somatic cell nuclear transfer (SCNT) technology would be impossible for him or her to have capability of giving consent to go through such research process. Although the same problem would arise in any medical research for therapeutic purpose on the unborn or young children, cloning research is different because, unlike situations in which parents give permission for an experimental intervention that aims to correct an existing problem in a fetus or child, no patient and hence no medical problem exist prior to the initiation of cloning research for any biomedical purpose. This is similar to the situation that a person's DNA is used to create one or more copies without that person's permission or perhaps even without his or her knowledge. If this scenario may raise issue of whether the autonomy for self-determination of that person is restricted, the cloned child's autonomy for self-determination on research or experiment may also be worth of equal concerned.

#### 2. Free Choices

However, the question of whether the concept of personal autonomy for selfdetermination on reproductive choice contains the choice of various facilities, including human cloning techniques, to successfully realize the reproductive right still remains unclear. If the reproductive right could be regarded as a positive right, it is the duty and obligation of the State to provide a variety of feasible opportunities to satisfy the need of its people to accomplish their autonomy for self-determination. On the other hand, if the reproductive right might only be considered as a negative right, it is then the duty and obligation of the State not to use unwanted power to interfere with the enjoyment of people to exercise their autonomy for selfdetermination on the choice of reproductive facilities. No matter which side we stand, personal autonomy for self-determination on reproductive decisions possesses highest moral value and deserves highest respect by others.

This question may also arise when the autonomy and self-determination of a human embryo is concerned. A cloned person who developed from a human embryo created in a laboratory is technically an artificial construct. Even if he or she gives birth and grows into a mature human, he or she is nevertheless) the result of deliberate human decision and action, and is therefore, through this arbitrariness, only an artifact. There is no chance other than random mutations to ensure that the clone is in any way genetically different from the donor of the nucleus. At this point, it is the most important argument for any ethical evaluation or legal ban on reproductive human cloning: it must not be permitted to impose the genetic identity of any individual on another without his or her informed consent.

By cloning, the clone creator would deny autonomy to the clone for purely selfish motives and would therefore violate the ethical maxim, which the great philosopher Immanuel Kant formulated two hundred and twenty years ago, drawing from his categorical Imperative: "[A]ct that you use humanity, whether in your own person or in the person of any other, always at the same time as an end, never merely as a means." Thus, every person must be as free as possible from the arbitrariness of others. This would of course extend to *in vitro* embryo splitting and subsequent implantation in the uterus with the sole purpose of deliberately creating monozygotic twins, because it also arbitrarily imposes genetic identity on a future human.<sup>178</sup>

### **C. Due Process**

<sup>&</sup>lt;sup>178</sup> See Christof Tannert, *Thou Shalt Not Clone: An ethical argument against the reproductive cloning of humans*, 7.3 EMBO REPORTS 238-240 (2006), also available at http://www.nature.com/embor/journal/v7/n3/pdf/7400653.pdf

A common understanding of due process in the principle of justice is that no person shall be deprived of life, liberty, or property, without due process of law.<sup>179</sup> The U.S. Supreme Court has understood due process to protect both substantive and procedural rights from unwarranted governmental intrusion. People's rights and liberties recognized by the Constitution may be guaranteed under substantive due process protection. On the other hand, procedural due process protection not only ensures that people's rights and liberties could be fairly realized without unreasonable infringement, but also requires that the government's decision-making processes which substantially affect rights and liberties of the people should be fair, just, and transparent. The Court further held that a person's right or liberty that can demonstrate the existence of human dignity of that person may be deemed fundamental. And any government infringement on that right or liberty would be subject to strict scrutiny of judiciary, i.e., the most rigorous form of judicial review applied by a reviewing court. Government action will survive strict scrutiny only if such action is a narrowly tailored means to accomplish a compelling state interest, such as national security, public health, and so forth.<sup>180</sup>

It is also notable that at present, the human cloning technology is not advanced enough to create any viable cloned human for reproductive purposes or any functional cloned embryos for research or therapeutic purposes, a due process challenge may not likely be ripped and justiciable,

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<sup>&</sup>lt;sup>179</sup> See U.S. CONT. Amends. V & XIV

<sup>&</sup>lt;sup>180</sup> See Roe v. Wade, 410 U.S. 113 (1973)

as there is no actual or imminence danger of injury against related rights and liberties or there is no actual case or controversy for the issue before the court.<sup>181</sup>

#### 1. Substantive Safeguards

In attempting to show that a right to clone for reproductive purpose is deeply rooted in our history and tradition. Proponents for reproductive human cloning technology have referenced identified reports of artificial insemination dating back to the 1790s and argued that assisted reproduction has been a part of the history. They also contend that the absence of state bans on *in vitro* fertilization (IVF) illustrated a continued unwillingness on the part of state legislatures to prevent infertile couples from exploring new reproductive technologies.<sup>182</sup>

Under substantive due process requirement, recognition of a fundamental right to clone for reproductive purpose would require the government to demonstrate a compelling state interest to justify any infringement on that right. Scholars have suggested at least two interests that are likely to be articulated. First, government could contend that a ban on reproductive cloning is necessary to prevent the conception of babies that would be plagued by physical disorders. Second, government could argue that a ban is necessary because cloned children would suffer social stigma and psychological harm. However, if it is determined that there is not

<sup>&</sup>lt;sup>181</sup> See Sheils v. University of Pa. Med. Ctr., 1998 U.S. Dist. LEXIS 3918 (E.D. Pa. 1998); 7 Am. Disabilities Cas. (BNA) 1499

<sup>&</sup>lt;sup>182</sup> See Note, Human Cloning and Substantive Due Process, 111 HARVARD L. REV. 2348, 2360-2361

a fundamental right to clone for reproductive purposes, it is likely that the government's interests in preventing harm to cloned children would adequately justify regulation. The articulated interests would probably survive rational basis review.<sup>183</sup>

Similar analysis may apply to the right to clone for therapeutic purpose. Proponents who insist that the fundamental right protection shall extend to human cloning for therapeutic purpose have characterized this right within the sphere of people's freedom of scientific inquiry. They maintain that freedom of scientific inquiry encompasses the right to acquire useful knowledge and has long been an enduring value for common goods of the humans as a whole. The existence of patent system is exactly an important evidence of our tradition of promoting and protecting scientific inquiry and invention.<sup>184</sup>

However, right to clone for therapeutic purpose would either not directly involve a person's choice and enjoyment of his or her right and liberty, or not be the kind of personal rights and liberties that would suggest inclusion as an essential part of human dignity. In addition, unlike reproductive human cloning, which could involve fundamental childbearing issues, therapeutic human cloning does not implicate similarly personal matters for scientists and other researchers. Therefore, the people's rights to health and the patients' rights to cure and

<sup>&</sup>lt;sup>183</sup> See Cass R. Sunstein, *Is There a Constitutional Right to Clone?* In U OF CHICAGO PUBLIC LAW RESEARCH PAPER NO. 22 (March 2002); also available at http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=304484

<sup>&</sup>lt;sup>184</sup> See Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HAR. J. L. & TECH. 643, 661 (1998)

treatment may be deserved to have been seriously concerned here. If such rights could be recognized fundamental, any restrictive governmental decision against the development and employment of therapeutic human cloning technology could be deemed infringement of those personal rights, and thus may be subject to judiciary strict scrutiny under substantive due process requirement. It is notable that although due process may not gravely weigh the interests of embryos or fetus being in research cloning processes, the reviewing court could still, based on humanitarian concerns and considerations, look upon the public policy issues on the dignity of an unborn human life.

#### 2. Procedural Safeguards

Concerning about the procedural due process in development and employment of human cloning technology, current international documents may provide certain effective safeguard models. Both the Universal Declaration on the Human Genome and Human Right (UDHGHR) and the 1997 European Convention on Human Rights and Biomedicine (ECHRB) require that all research, including that initiated by profit-making funders, to undergo scientific and ethical review for the protection of participants.<sup>185</sup> The European Convention further mandates public discussion of fundamental questions raised by biomedicine.<sup>186</sup> Public involvement in

<sup>&</sup>lt;sup>185</sup> See Universal Declaration on the Human Genome and Human Right, Art. 5 (d); European Convention on Human Rights and Biomedicine, Art. 16 (iii)

<sup>&</sup>lt;sup>186</sup> See European Convention on Human Rights and Biomedicine, Art. 28

policymaking is also mentioned in the International Covenant on Economic, Social, and Cultural Rights (ICESCR) General Comment on the right to health. Based on that document, a core and non-derogable obligation of States parties is to adopt a national public health strategy that addresses the health concerns of the whole population and that is devised and periodically reviewed, using a participatory and transparent process.<sup>187</sup>

## **D. Equal Protection**

The concept of equal protection in principle of justice is that all people shall enjoy equal protection of the laws. This means that the State must apply the law equally to all people and may not give preference to one person or class of persons over another. It is well settled that a law may violate equal protection requirement if the law infringes upon a person's fundamental right through unequal treatment, only based upon race, color, origin, nationality, language, sex, gender, legitimacy, or other unjustifiable classifications with similar status and value.<sup>188</sup>

Since it is expectable that at present no cloned person may be legally or morally created through contemporary level of human cloning technology, any equal protection challenge based

<sup>&</sup>lt;sup>187</sup> See Committee on Economic, Social, and Cultural Rights (CESCR), General Comment No.14 (2000) (E/C.12/2000/4), Para. 43 (6).

<sup>&</sup>lt;sup>188</sup> See Skinner v. Oklahoma, 316 U.S. 535 (1942) (In this case, the U.S. Supreme Court struck down an Oklahoma law requiring forced sterilization of certain convicted habitual criminals. The Court held that the right of procreation was a fundamental right; hence, the sterilization law, which denied the fundamental right of procreation, was subject to strict scrutiny.)

on an unwarranted classification between cloned and non-cloned persons would be considered fictional and illusory and deserve no immediate review by the courts.

#### 1. All Reproductions Treated Equal

Consider the legal status of sexual reproduction. Though the law occasionally prohibits sexual intercourse in certain contexts, it does not prohibit sexual reproduction as such. Indeed, the right to procreate and found a family has been identified as a fundamental human right.<sup>189</sup> As a result of this laissez-faire attitude, humans born through sexual reproduction steadily increase in number. They do not suffer legal burdens on account of their origin in sexual reproduction. By contrast, anti-cloning laws ban asexual reproduction outright. To the extent they can be enforced, the laws will reduce the number of human clones who are conceived, gestated, and born. Although cloned human embryos or fetus may not qualify as persons entitled to equal protection against discrimination, cloned babies and children born in disobedience to cloning banning regulations are fully entitled to enjoy such protection. Thus, to review whether an anticloning law violates the clones' equal protection rights, it is important for the reviewing court to identify the burdens that the laws in question will impose on them from the moment of their birth.190

#### 2. All People Created Equal

<sup>189</sup> Id.

<sup>&</sup>lt;sup>190</sup> See Kerry Lynn Macintosh, Human Clones and International Human Rights, 7 UTS L. REV. 134 (2005)
Equal protection also sets up the rule recognized as a universal norm that all people are created equal. This norm is put at risk by research cloning which would create, use, and destroy embryonic human beings. Once human life has been created, proponents of its use and destruction must convince the public that there is a reason to deny the protection we give to every other human life. They may only do so by arguing that some lives are not worthy of protection. But this is an unpersuasive argument for it leaves to the powerful to discretionally decide who should be protected. Consequently, the principle of parity and equality among human beings may be violated by the possibility that one person unjustly dominates another person without good cause.

On their face, laws that ban human reproduction cloning may not directly classify human clones. Instead, the laws prohibit scientists, doctors, parents, and other individuals from engaging in reproductive human cloning technology. Resultantly, they are subterfuges designed to impose hidden burdens on a class of prospect humans whose life are unpopular to some other human beings.<sup>191</sup> Would the equal protection requirement apply here? If the equal protection guarantee should extend to any human life either before or after birth, should the classification employed in the laws which has discriminate effect on the prospect humans created through cloning technology be subject to strict scrutiny by the reviewing court? Anti-cloning laws may

<sup>&</sup>lt;sup>191</sup> See KERRY LYNN MACINTOSH, ILLEGAL BEINGS: HUMAN CLONES AND THE LAW 154-155 (Cambridge University Press, 2005)

survive strict scrutiny only if the laws demonstrate that they serve a compelling state interest and they are narrowly tailored to serve those interests. In other words, the State must advance its compelling interests by the least restrictive means. The basic analysis and standard of judicial review applied to the equal protection requirement is the same as that applied to the due process requirement.<sup>192</sup>

Based on equal protection analysis, a law prohibiting cloning for everyone could still have chance to survive in the strict scrutiny by the judiciary. First, such a law would prevent anyone, married or single, heterosexual or homosexual, from cloning. Accordingly, it would not treat differently only based upon the status of the persons involved. Second, the distinction between cloning and other assisted reproductive technologies (ARTs) is permissible as long as it is based upon some compelling or important state interest. A ban on cloning may be considered as a narrowly tailored and least restrictive means to advance a State's compelling interest in safeguarding the well-being of children by preventing the use of such technology that may result in physical, psychological, or social harms to them.<sup>193</sup> However, if one day the benefits of such cloning technology we may take outweigh the risks that we may suffer, then the decision of the reviewing court may be different.

<sup>&</sup>lt;sup>192</sup> See Buckley v. Valeo, 424 U.S. 1, 93 (1976)

<sup>&</sup>lt;sup>193</sup> See Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76.6 THE GEORGE WASHINGTON REV. 1457, 1479-1480 (September 2008)

## 3. All Health Cares Accessed Equal

Even in the laws which grant limited application of biomedical or therapeutic cloning technology, the equal protection guarantee issues may still be relevant. Who would stand to benefit from such research cloning? The 1997 European Convention on Human Rights and Biomedicine (ECHRB) refers to the duty of parties to provide "[E]quitable access to health care of appropriate quality."<sup>194</sup> The Universal Declaration on the Human Genome and Human Rights (UDHGHR) also declares that "[B]enefits from advances in biology, genetics and medicine... shall be made available to all."<sup>195</sup> The setting of research agendas is usually a matter of scientific freedom, but if objectives of global health seem unachievable through the market, then considerations of equity come to bear on priorities in allocating resources.

To reduce health disparities, an affirmative-action policy could direct public funding for research so as to prioritize the needs of vulnerable groups.<sup>196</sup> However, some research especially in cloning which involves quite a few unsettled moral or policy issues may not go forward without private funding. At this point, priorities could be set for public-private collaboration in promoting certain research which involves less controversial problems. To fulfill equal treatment obligation, the State should provide sufficient opportunities and facilities for the

<sup>&</sup>lt;sup>194</sup> See J. RAWLS, A THEORY OF JUSTICE (Harvard University Press, 1971); also see Carmel Shalev, *Human Cloning* and Human Rights: A Commentary, 6.1 HEALTH AND HUMAN RIGHTS 137, 143 (2002)

<sup>&</sup>lt;sup>195</sup> See Universal Declaration on the Human Genome and Human Rights, Art. 16 (a)

<sup>&</sup>lt;sup>196</sup> See WORLD HEALTH ORGANIZATION, GENOMICS AND WORLD HEALTH 129-130 (Geneva, 2002)

participants and the public to have informed knowledge and discussion on the matters of the affordability and accessibility of the related resources.

## IV. Conclusion

In centuries the concepts of rights and liberties have evolved to a variety of aspects. Only those rights and liberties that could be recognized as fundamental may be safeguarded by highest protecting mechanism in every country. Human cloning is a novel scientific technology that has emerged in late twentieth century. Although this technology is not advanced enough to apply to the humans, a few rights and liberties, no matter whether they are traditional or newlydeveloped, personal or collective, may be influenced by it.

Unlike other historical changes in the past, the human cloning technology involves a lot of uncertainties, ambiguities, and dilemmas that have never been encountered before. Its development results in great tensions between God the Creator and humans, nature and intelligence, morality and science, and so forth. Many countries and the international community as well apparently cannot reach a consensus approach to carry out issues and problems incurred from this technology. Every matter looks important but the value to the future of humanity is still unclear. Currently the most urgent need in regime of law and public policy seems to be that of reestablishing the harmony between the demands of scientific inquiry and the safeguards of human values. The scientist cannot regard the moral rejection of human cloning as an embarrassed grand-old gossip only. Moreover, there may be a situation for advancing scientific research, including human cloning, if it could answer an indispensible need or provide a significant benefit for humanity or for every living being. To enable biomedical science to maintain and strengthen its relationship with the true welfare of the humans and the society, it is necessary to foster a thoughtful outlook on legal and policy aspects in a context of solidarity between science, the public interest, and the common good.

## <u>Chapter 5</u>

# <u>Regulatory Consensus on Human Cloning Technology in the</u> <u>International Community</u>

## I. Introduction

Following the first successful birth of a cloned mammal, Dolly the sheep, in 1997, the international community became seriously concerned about the application of technique to human beings. Responding to such public fears, certain countries rapidly moved to prohibit human reproductive, whether by official statement, decree or law. Some countries have introduced legislation regulating human cloning with explicit wording, while others reviewed their existing national legislation and concluded that it can be interpreted as implicitly regulating of human cloning. A prohibition on genetic manipulation of embryos or germ-line intervention in medically assisted reproduction is interpreted as implicitly prohibiting human reproductive cloning.

At present, there is no country which permits reproductive cloning of human beings by legislation or guidelines. Concerning the prohibition of this practice, three approaches appear in existing national legislation as follows: Prohibit the creation of clone embryo (by embryo splitting or by somatic cell nuclear transfer); Prohibit the implantation of a clone embryo into a uterus; and Without specifying the method, prohibit any attempt to artificially create a human being genetically identical to another human being (embryo or fetus) alive or dead.

Concerning therapeutic cloning on the other hand, different positions and regulations are observed in various national legislations. Regulations on somatic cell nuclear transfer (SCNT) for embryo creation are rarely mentioned in the legal text but creation of such embryos are generally regulated under embryo research. Currently, there exist three different approaches on embryo research: Generally prohibit research on embryos (with some specific exceptions) and/or creation of embryos for research purposes; Permit research on supernumerary embryos produced by fertility treatment but prohibit creation of embryos for research purposes; and Permit creation of embryos for research purposes with strict conditions. The first and second approaches are interpreted as prohibiting therapeutic cloning and the third approach is understood as possible permission for therapeutic cloning depending on the conditions provided for embryo research.

Nevertheless some ambiguity persists in the first approach when exceptions to the prohibition on embryo research are provided for the purpose of "research for preventing or treating diseases" or "research for therapeutic purposes." Some countries read this exception as permission for therapeutic cloning. Certain countries are reviewing and amending such text in the existing legislation to clarify the position on therapeutic cloning. Further efforts to clarify the national position on therapeutic cloning by reviewing or amending existing legislation should be encouraged since this technique is relatively new and some legislative texts do not anticipate the application of such a technique.

Although different positions exist concerning the regulation of human cloning techniques employed for therapeutic purposes, there is no country which permits the practice of human reproductive. It is clear that an international consensus rejecting human reproductive under current circumstances has emerged. However, further implement this consensus position into national legislation remains a primary goal. This chapter is intended to review contemporary regulatory mechanisms concerning human cloning technology, both for reproductive and for therapeutic purposes. The feasibility and possibility of more effective regulatory approaches in the international community would also be considered here.

## II. Current Regulatory Regime towards Human Cloning Episode

## A. National Level

From the viewpoint of respective nations or districts, although different policies and laws are currently being formulated in different countries, the objectives of national situations are largely similar, i.e., to protect the dignity of all persons in relation to the use of human genetic materials. It is acceptable among nations that cloning is deemed to diminish the value of human dignity and violate basic norms of the respect for human life and the integrity of the human species. However, it is also recognized by many experts and professionals that pursuing stem cell research will not inevitably lead to human reproductive cloning. Although human cloning technology may be unethical in many aspects and dangerous as a novel precedent, it is also true that not everything that is immoral ought to be prohibited by law. This situation shows how different countries treat human cloning technology in different ways in their own particular jurisdiction.

The first category countries that have legislation or regulation prohibiting both reproductive human cloning and other non-reproductive human cloning are the vast majority. Australia, Austria, Canada, Demark, France, Germany, Iceland, Ireland, Japan, Mexico, Norway, Peru, Spain, Sweden, and Switzerland are in the first category. Netherlands has legislation or regulation prohibiting reproductive human cloning and imposing a moratorium on non-reproductive human cloning.

Most of the remaining countries belong to the second category and have legislation or regulation prohibiting reproductive human cloning but permitting other non-reproductive human cloning. Belgium, China, India, United Kingdom are in the second category. Countries that have legislation or regulation prohibiting reproductive human cloning but not covering or still keeping silent on other non-reproductive human cloning are legally deemed as the second category countries. Finland, Greece, Israel, Korea, and New Zealand are among these countries. Russia imposes a moratorium on reproductive human cloning but still keeps silent on other nonreproductive human cloning.

The third category countries that have no substantive legislation or regulation prohibiting or permitting any forms of human cloning are in the minority. Luxembourg, Portugal, and Thailand are in the third category. The United States has no substantive legislation or regulation prohibiting or permitting any forms of human cloning but her states have legislation or regulation prohibiting reproductive human cloning or both reproductive human cloning and other non-reproductive human cloning.<sup>197</sup>

As a whole, relatively few countries regulate on reproductive and therapeutic cloning. The debate concerning a regulatory framework at the national level should be further

<sup>&</sup>lt;sup>197</sup> See Shaun D. Pattinson & Timothy Caulfield, Variations and Voids: the Regulation of Human Cloning around the World, 5 BMC MED ETHICS 9 (2004), Published online at http://www.pubmedcentral.nih.gov/articlerender.fcgi? Artid=544897

encouraged. Following is an overview of selective national legislations, governing guidelines and some opinions relating to matters directly or indirectly relating to the human cloning technology.<sup>198</sup>

### 1. European Nations

**Belgium:** Article 6 of The Law on Research in Embryos in Vitro of 11 May 2003 states in Article 6 that: "Human reproductive cloning is prohibited." Article 3 allows research on embryos *in vitro* for therapeutic purposes as well as for cloning research only where no other method of comparable efficacy is available and under strict conditions, notably if research takes place in accredited university laboratories with local and federal oversight on embryos within their first 14 days of development. Article 4, Section 1 prohibits the creation of embryos for research purposes, except when the research goal cannot be achieved by research on supernumerary embryos and when the same strict conditions applicable to embryos in vitro under Article 3 are fulfilled. It is also noted that, based on a respect-for-life consideration, Article 5, Section 2 declares that "Embryos on which research has been conducted should not be

<sup>&</sup>lt;sup>198</sup> See UNESCO, NATIONAL LEGISLATION CONCERNING HUMAN REPRODUCTIVE AND THERAPEUTIC CLONING, July 2004, posted at http://unesdoc.unesco.org/images/0013/001342/134277e.pdf

placed into a woman except when the research had a therapeutic goal for the embryo itself or when it concerns an observational method that does not harm the integrity of the embryo."<sup>199</sup>

**Denmark:** Under Act No. 503 on the Scientific Ethics Committee System and the Examination of Biomedical Research Projects of 1992, research on cloning (production of genetically identical individuals) is forbidden. Act No. 460 on Medically Assisted Procreation of 1997, in connection with medical treatment, diagnosis, and research, further forbids research on human reproductive cloning and somatic cell nuclear transfer in therapeutic cloning. However, the 1997 Act was amended in June 2003 by Act No. 427, allowing research for therapeutic purposes for supernumerary embryos from *in vitro* fertilization (IVF) treatment and derived stem cells. All such research requires prior approval under the established committee system.

**Finland:** Under Sections 13 and 26 of the Finnish Medical Research Act (488/1999), research with the aim of cloning human beings is prohibited, as is the production of embryos exclusively for research purposes. Section15 states that research on embryos and gametes in order to modify hereditary properties is also prohibited, unless the research is aimed at curing or preventing a serious hereditary disease. However, the Act has been interpreted as allowing therapeutic cloning under the conditions set forth in sections 11 through 13. Those found in violation face fines or imprisonment.

<sup>&</sup>lt;sup>199</sup> See Law on Research in Embryos In Vitro (11 May 2003), Articles 3-6 An excerpt text in English is available at http://www.hinxtongroup.org/wp\_eu\_exc.html

**France:** At the request of President Chirac, the National Consultative Ethics Committee on Health and Life Sciences (CCNE), released its Opinion No. 54 of 22 April 1997 concluding that "an attempt at identical reproduction of human beings whose genome would no longer be the result of the lottery of heredity and instead depend on another's will, would seriously endanger essential original indetermination as well as other fundamental traits of a person" and called for global collaborative efforts against reproductive cloning. In July 1994, the Bioethics law which regulates practices in the fields of medicine, reproductive technologies, genetics and organ donation was adopted. Certain articles of the health code, penal code, intellectual property code and civil code relevant to the human body are included in the Bioethics law. In July 2004, the revised Bioethics law was adopted after a lengthy and intensive discussion. The new law explicitly prohibits human cloning both for reproductive and therapeutic purposes.

In respect of reproductive cloning, Article 21 states: "Any intervention designed to produce a child who is genetically identical to another person, dead or alive, is prohibited." In addition, therapeutic cloning is addressed as follows. Article 25 states: "Any creation of a human embryo by fertilization or by cloning for research purposes is prohibited. Creation of a human embryo by fertilization or by cloning for commercial or industrial purposes is prohibited. Equally, any creation of a human embryo by cloning for therapeutic purposes is prohibited." With regard to research on embryos in general, Article 25 also declares that "Research on human embryos is prohibited."

At the same time, the Law also describes very limited exceptions to the application; including government authorized research carried out within five years from the date of entry into force of the law and only if the research is likely to lead to "major therapeutic progress" where no other available method "offers comparable effectiveness." Nevertheless, the creation of human embryos for the sake of either research or procreation must remain severely dismissed and firmly sanctioned by imprisonment up to seven years and a heavy fine. The exception prescribed above is only permitted using embryos created *in vitro* for the purpose of procreation and which are no longer used for this purpose, given informed consent by the donors. In any case, such research requires authorization from the Agency of biomedicine established by the Law.

**Germany:** The Federal Embryo Protection Act of 1990 (Embryonenschutzgesetz) which limits the scope of embryo research, is currently considered a basic regulatory measure for the protection of human embryos. It explicitly prohibits attempts at cloning of humans for any purposes. Section 6 (1) of the Act reads: "Anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person will be punished with imprisonment up to five years or a fine. (2) Likewise anyone will be punished who transfers into a woman an embryo designated in paragraph 1. (3) Any attempt is punishable.<sup>200</sup> Thus, weighing the human dignity and human life against the interests of research and science, unless for implantation into its mother's uterus with the intention of pregnancy or birth, the creation and utilization of any human embryo either for reproductive or for therapeutic purpose is prohibited under this Act.

However, Section 4 of the Stem Cell Act (Stammzellgesetz) of 2002 permits the importation and utilization of embryonic stem cells that were derived, before 1 January 2002 in the country of origin in accordance with relevant national legislation there and are kept in culture or are subsequently stored using cryopreservation methods (embryonic stem cell line), from the embryos that had been produced by medically-assisted in vitro fertilization in order to induce pregnancy and were definitely no longer used for this purpose and that there is no evidence that this was due to reasons inherent in the embryos themselves, upon approval by a competent agent for every single case.<sup>201</sup>

To ensure protection of embryos in connection with the importation and utilization of human embryonic stem cells, Section 5 of the same Act further reads that "Research involving embryonic stem cells shall not be conducted unless it has been shown by giving scientific

<sup>&</sup>lt;sup>200</sup> For the full text in German, see Federal Embryo Protection Act 1990 at http://bundesrecht.juris.de/bundesrecht/ eschg/gesamt.pdf

<sup>&</sup>lt;sup>201</sup> See Stem Cell Act of 28 June 2002, Section 4, Paragraph (2), Sub-paragraph 1 (a) and (b), available at http://www.bmj.bund.de/files/-/1146/Stammzellgesetz%20englisch.pdf

reasons that -1... serves eminent research aims to generate scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans...<sup>2202</sup>

**Greece:** The General Council for Health Statement of 1988 explicitly prohibits reproductive cloning. The recently adopted law 3089/2002 on Medically Assisted Human Reproduction *inter alia* prohibits explicitly reproductive cloning by stating that "human reproduction with the methods of cloning prohibited". According to this law, creation of embryos can be permitted only "in order to treat the incapacity to have children by natural way or to avoid the transmission of a severe disease to the child". Nevertheless research on embryos using supernumerary embryos is allowed for therapeutic purposes.

**Iceland:** Article 12 of the Act on Artificial Fertilization (55/1996) prohibits to: "a) cultivate or produce embryos solely for research purposes; d) perform cloning. Research on embryos is generally prohibited by Article 11, with exceptions for "a) if it is part of an in vitro fertilization treatment; b) if the intention is to diagnose hereditary diseases in the embryos themselves; c) if the purpose is to advance the treatment of infertility, or; d) if the purpose is to improve understanding of the causes of congenital diseases and miscarriages." Violators face fines or imprisonment.

<sup>&</sup>lt;sup>202</sup> Id., Section 5, Paragraph 1

**Italy:** Awaiting the approval of a controversial law on assisted reproduction, the Ordinance of 5 March 1997 on the prohibition of practices of human or animal cloning was enacted. Article 1 of the Ordinance states: "Any form of experimentation or intervention, however practiced, with the goal, even indirect, of human or animal cloning is prohibited." The proposed legislation would include imprisonment of up to 20 years and heavy fines for "anyone who realizes a project which aims to obtain a human being from one starting cell, genetically identical to another human being, alive or dead."

**Netherlands:** The Embryos Act, which prohibits human reproductive cloning and strictly regulates research on embryos, was adopted in July 2002. The law allows for staggered dates for entry into force by section, to be determined by Royal Decree. Section 24(a), lapsing no longer than five years after entry into force, prohibits the creation or use of an embryo for research purposes other than the induction of a pregnancy. Section 24(f) prohibits performing procedures with gametes or embryos with a view to the birth of genetically identical human individuals. Violations are punishable by up to one year in prison or a "fourth category" fine. Once Section 24(a) has lapsed, Sections 9, 24(b) and 11 shall apply, prohibiting the creation and use of an embryo specifically for cloning research, except where such research is reasonably likely to lead to new insights in the fields of infertility, artificial reproduction techniques, hereditary or congenital diseases or transplant medicine and can only be performed by making

use of such embryos. Section 9 (1) states that the use of any such specially created embryo for non-reproductive purposes must be made available by "adults who are capable of making a reasonable assessment of their interests in this regard."

**Norway:** Chapter 3 of Law No. 56 of 1994 on the medical use of biotechnology prohibits research on embryos as well as the use of techniques aimed at the production of genetically identical individuals. In July 2002, the Government presented a bill to the Parliament proposing an explicit prohibition against the use of therapeutic cloning as a method to produce embryonic stem cells for medical research.

**Russian Federation:** In April 2002, the Law on the Temporary Prohibition of Human Cloning was adopted. Under this law, creation of "a human being, genetically identical to another one, dead or alive, by means of implantation of a human body cell into a female gamete preliminarily deprived of its nucleus" is subject to a temporary five-year ban. The law also forbids import and export of human clone embryos for the same period. Persons violating the law will be prosecuted under federal law. However, neither the Criminal nor Administrative Codes specify the punishment for cloning acts.

**Spain:** Spain was the first country to pass a separate law that exclusively dealt with the field of human procreation techniques. Article 16 of the Spanish Penal Code and Chapter VI, Article 20 of Law 35/1988 on the medically assisted human reproduction techniques (ART)

make the creation of identical human beings by cloning or any other technology for race selection purposes a serious infringement on or collusion with human rights and individual dignity, with criminal sanctions by imprisonment from one to five years. Chapter II of the Law 35/1988 also prohibits any attempt to create embryos with or without fertilization for any end other than procreation.<sup>203</sup>

Similarly, Law 42/1988 on the Donation and Utilization of Human Embryos and Fetuses or of their Cells, Tissues or Organs protects the post-implantation embryo and regulates the donation and use of human embryos and fetuses and the cells, tissues or organs there from. It generally prohibits any experiments with living embryos or fetuses. Among the "very serious offences" are the performance of any activity which is aimed at modifying the non-pathological human genetic patrimony; the creation and maintaining of live embryos or fetuses inside the uterus or outside of it with any purpose than that of procreation; the experimentation with live embryos or fetuses. <sup>204</sup> Articles 2(e) and 8(a) of the Law also prohibit research on the creation or production of "genetically identical human beings." This appears to allow therapeutic cloning for the purpose not to produce a child.<sup>205</sup>

<sup>&</sup>lt;sup>203</sup> See Law No. 35/1988 of 22 November 1988 on Assisted Procedures, (1989) 40 (1) *IDHL* 82

<sup>&</sup>lt;sup>204</sup> See Law No. 42/1988 of 28 December 1988 on the Donation and Use of Human Embryos and

Fetuses or their Cells, Tissues, or Organs, (1991) 42 (1) IDHL 64

<sup>&</sup>lt;sup>205</sup> See JOHN CHARLES KUNICH, THE NAKED CLONE, HOW CLONING BANS THREATEN OUR PERSONAL RIGHTS 71 (Praeger Publishers, 2003)

Nowadays, there is an increasing demand for human embryos for research purposes. Besides the research to improve ART, stem cells research is becoming a very important scientific issue for the future of regenerative medicine. The use of surplus embryos will provide an important source of stem cells in order to obtain cell lines for transplantation. The possibility of using them for this purpose is considered as a great valuable contribution for the development of future regenerative medicine. Having in mind all these considerations, the majority of the members of the National Committee of Human Assisted Reproduction (CNRHA) thinks that to carry out research on frozen embryos, when all other possible alternatives have been tried and when the only alternative is their destruction, is not against the respect that all human embryos deserve. In consequence, the Committee recommends that research on surplus frozen embryos should be authorized as an alternative to destruction when the legal limit period has expired and considers that a modification of the current rule is necessary.

Sweden: Law 115 of March 1991 concerning measures for the purposes of research or treatment in connection with fertilized human oocytes implicitly prohibits embryo and oocyte cloning with criminal sanctions. It states that the purpose of experimentation shall not be to develop methods aimed at causing heritable genetic effects. In December 2001, the Swedish

<sup>&</sup>lt;sup>206</sup> See Barri P.N, Boada M., Veiga A, Spanish Regulations on Assisted Reproduction Techniques, in ESG NEWSLETTER, 22 February 2009, at http://www.seg-web.org/index.php/lang-en/newsletter-de-la-seg/88-spanish-regulations-on-assisted-reproduction-techniques?c63fdbb9eac0e43277d9e5dbcea77d4b=a903aeb121034b5c30edb b622e4eaebdf

Research Council declared that creating embryos through somatic cell nuclear transfer for therapeutic purposes "can be ethically defensible" but would first necessitate the formulation of a legal framework by the Swedish government.

**Switzerland:** The Federal Constitution explicitly prohibits all forms of cloning. Article 119, Paragraph 2 reads: "All forms of cloning and interference with genetic material of human reproductive cells and embryos are prohibited." The Federal Law on Medically Assisted Procreation of 1998 (SR.814.90) which took effect on 1 January 2001 explicitly prohibits embryo and oocyte cloning with criminal sanctions. In its message to Parliament in November 2002 regarding the law on embryo research, the Federal Council indicated that Article 119, paragraph 2 of the Federal Constitution also bans therapeutic cloning.

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**United Kingdom:** Article 1(1) (a) of The Human Fertilisation and Embryology Act (HFEA) of 1990 defined a human embryo as "a live human embryo where fertilization is complete."<sup>207</sup> Following the decision of the High Court on 15 November 2001 that Britain has no law governing the reproduction of human embryos and embryos created by cloning techniques such as cell nucleus replacement, i.e., somatic cell nuclear transfer (SCNT), were not regulated by this Act, the Human Reproductive Cloning Act 2001 was enacted in December 2001.

The Act explicitly prohibits reproductive cloning by stating in article 1 that "(1) A person who places in a woman a human embryo which has been created otherwise than by fertilization is guilty of an offence. (2) A person who is guilty of the offense is liable on conviction on

<sup>&</sup>lt;sup>207</sup> See Human Fertilisation and Embryology Act 1990, Article 1(1)(a), also available at http://www.opsi.gov.uk/ acts/acts1990/Ukpga\_19900037\_en\_1

indictment to imprisonment for a term not exceeding 10 years or a fine or both...<sup>208</sup> The Act was enacted to strictly illegalize the cloning techniques that were intended to reproduce a child, but take into account scientific advances, stem cell experiments in particular. It was specifically worded to allow cloning to create embryos for stem cell research. However, this Act contained no definitions for any terms of it, thereby creating the possibility of controversy over the meaning of terms such as "human embryo."<sup>209</sup>

In January 2002 the Court of Appeals overturned the High Court decision of 15 November 2001, ruling that clones produced by cell nuclear replacement can be classified as embryos, thus coming under the regulations of the Human Fertilisation and Embryology Act (HFEA) of 1990 which allows creation of and research on embryos before the appearance of the primitive streak. Pursuant to the Act, a Code of Practice was produced by the Human Fertilisation and Embryology Authority, which permits embryo research for the following purposes: To promote advances in the treatment of infertility; To increase knowledge about the causes of congenital disease; To increase knowledge about the causes of miscarriages; To develop more effective techniques of contraception; and To develop methods for detecting the presence of gene or chromosome abnormalities.

<sup>&</sup>lt;sup>208</sup> See Human Reproductive Cloning Act 2001, Article 1, available at http://www.opsi.gov.uk/acts/acts2001/ ukpga\_20010023\_en\_1

<sup>&</sup>lt;sup>209</sup> See JOHN CHARLES KUNICH, THE NAKED CLONE, HOW CLONING BANS THREATEN OUR PERSONAL RIGHTS 67-68 (Praeger Publishers, 2003)

In 2001, new regulations were made to allow creation of embryo for the following purposes: To increase knowledge about the development of embryos; To increase knowledge about serious disease; To enable any such knowledge to be applied in developing treatment for serious disease. This amendment together with the decision of the Court in January 2002 therefore opened the way for the Human Fertilisation and Embryology Authority to require a license for therapeutic cloning.

#### 2. Asian Nations

**China:** The Ministry of Public Health released Rules on Assisted Reproductive Technologies for Human Beings in August 2003, which went into force in October 2003. The regulations in Paragraphs 3.7 and 3.15 prohibit human reproductive cloning stating that "the performance of cytoplasm transfer and germinal vesicle transfer for infertility treatment is forbidden and the (reproductive) cloning of human beings is forbidden." At the same time, the Ministry of Health released Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank in August 2003, which also entered into effect in October 2003. Paragraph 1.3.g states that "cytoplasm transfer and germinal vesicle transfer should not be allowed for infertility treatment before the problem of safety is resolved." The guidelines allow cloning research for therapeutic purposes. In Hong Kong, Human Reproductive Technology Ordinance was enacted in June 2000. Section 15 of the Ordinance states: "No person shall -(...) (a) for the purposes of embryo research - (i) bring about the creation of an embryo; (e) replace the nucleus of a cell of an embryo with a nucleus taken from any other cell; or (f) clone any embryo."

India: In 2000 the Indian Council of Medical Research issued a Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects. The section addressing genetics states: "Since its safety, success, utility and ethical acceptability is not yet established, research on cloning [through nuclear transplantation or embryo splitting] with intent to produce an identical human being, as of today, is prohibited." Indian government's ethical policy document on the human genome, genetic research and services prohibits reproductive cloning, but opens the door to therapeutic cloning considered on a case-by-case basis by the National Bioethics Committee.

**Israel:** The 1998 Prohibition of Genetic Intervention Law No. 5759 (Human Cloning and Genetic Modification of Reproductive Cells Act) states that, during a period of 5 years, no act of intervention on human cells will be carried out, if the purpose of such intervention is either to clone a human being or to bring about the creation of a human being through the use of reproductive cells which have undergone a permanent intentional genetic modification. Thus, no human reproductive cloning was allowed during the five-year moratorium period. Article 6 of the Law establishes criminal sanctions with a prison sentence of two years. However, Section 5 sets forth a special exemption to this general prohibition which the Minister of Health may permit the creation of a human being through the use of genetically modified reproductive cells, if he/she finds that no harm will be caused to human dignity.

**Japan:** The Diet of Japan enacted the Law Concerning Regulations Relating to Human Cloning Techniques and other Similar Techniques was passed in November 2000 and took effect in June 2001. It prevents the birth of a cloned human by prohibiting transplantation of clone embryos to a uterus of a woman or an animal. The term "embryo" is defined in Article 2(1)1 as "A cell (except for a germ cell) or cells which has/have potential to grow into an individual through the process of development *in utero* of a human or an animal and has/have not yet begun formation of a placenta." Article 3 further reads: "No person shall transfer a human somatic clone embryo, a human-animal amphimictic embryo, a human-animal hybrid embryo or a human-animal chimeric embryo into a uterus of a human or an animal."

Accordingly, the Act prohibits any type of transfer of a human clone embryo into any kind of uterus. The reason for this prohibition was that the transfer of these embryos leads to the production of an individual with the same genetic structure as another specific individual (in the case of a human somatic clone embryo) or an embryo belonging to a subspecies of humans (in the case of the other three embryos). However, Supplementary Provision for Article 2 of the Law declares that the government shall, within three years of enforcement of this Law, take necessary measures in accordance with the results of its study and examination on the provisions under this Law, on the basis of the results of the study and examination by the Council for Science and Technology Policy, Cabinet Office concerning the method of handling of a human fertilized embryo as the beginning of a human life (i.e., human reproductive cloning technology) with consideration to the circumstances in which this Law is enforced or to any change of the situation surrounding the cloning techniques and other similar techniques. At present, it has been carefully executed not to bar work on therapeutic cloning unrelated to reproductive cloning of humans. It is also noted that Article 16 of the Act imposes punishments for violation of Article 3 with imprisonment for not more than ten years, or a fine of not more than ten million yen, or with both of these penalties cumulatively.<sup>210</sup>

The production of clone embryos and embryo research are regulated by the Guidelines in Relation to Handling of Specified Embryos, issued by the Minister of Education, Culture, Sports, Science and Technology. According to Article 7(1) of the guidelines promulgated in December 2001, research on specified embryos is allowed only using supernumerary embryos, in which the primitive streak does not appear, resulting from *in vitro* Fertilization (IVF) treatment within the

<sup>&</sup>lt;sup>210</sup> See The Law Concerning Regulations Relating to Human Cloning Techniques and other Similar Techniques, Articles 2, 3, & 16 Full text in English at http://www.ruhr-uni-bochum.de/kbe/4\_houritu.pdf

first 14 days of development from the date of production.<sup>211</sup> In July 2004, the Bioethics Committee of the Council of Science and Technology released a report, which concluded that the creation of embryos for research purposes including clone embryos should be permitted under strict conditions and creation of a monitoring system should be urged. Acting on this report, the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare will work towards revising current guidelines in this line.

**Singapore:** On 21 June 2002 the Bioethics Advisory Committee of Singapore (BAC) released a report on "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning." The BAC recommends a complete ban on reproductive cloning and would permit therapeutic cloning only under strict regulations. Recommendation 7 states: "There should be a complete ban on the implantation of a human embryo created by the application of technology into a womb, or any treatment of a human embryo intended to result in its development into a viable infant." The report also concluded that creation of human embryos either by IVF (*in vitro* Fertilization) or by SCNT (Somatic Cell Nuclear Transfer) for research purposes can only be justified where (1) there is strong cloning merit in, and potential medical benefit from, such research; (2) no acceptable alternative exists, and (3) on a highly selective,

<sup>&</sup>lt;sup>211</sup> See The Guidelines in Relation to Handling of Specified Embryos, Article 7 (1) Full text in English at http://www.lifescience.mext.go.jp/files/pdf/30\_82.pdf

case-by-case basis, with specific approval from the proposed statutory body. On 18 July 2002, the government approved the BAC recommendations.

**South Korea:** Bioethics and Biosafety Act strictly prohibiting reproductive cloning under any circumstances, subject to criminal sanctions for up to 10 years in prison, while regulating experiments that use embryonic stem cells and creating a national bioethics committee to oversee such research was adopted by the National Assembly in late December 2003. According to the Act, the creation of embryos for purposes other than infertility treatments is prohibited. Only supernumerary embryos produced for infertility treatments can be used for research. However, the government will approve limited research on somatic cell nuclear transfer (SCNT) based on the guidelines drawn up by the National Ethics Committees.

**Thailand:** The Medical Council of Thailand released the regulations on Human Cloning in June 2002 (No. 21/2544) which indicates the prohibition of reproductive human cloning. Furthermore, the Stem Cell Guideline produced in November 2003 by the Bioethics and Advanced Biomedical Research Project managed by the National Center for Genetic Engineering and Biotechnology (BIOTEC) and the National Health Foundation (NHF) also indicates the prohibition of reproductive human cloning.

#### 3. American Nations

**Argentina:** By a decree of March 1997, the President of Argentina declared all cloning experiments in connection with human beings to be prohibited and requested that the Ministry of Health and Social Action prepare a draft bill to that effect. Three relevant bills, No. 100/03 (2003), No. 827/00 (2000), and No. 0269-D-01 (2001) are today before the national parliament. At the local government level, two provinces have enacted laws specifically prohibiting cloning experiments involving human beings and human reproduction through cloning within their territorial boundaries: one is law No. 6581 of 1998 in Mendoza province and the other is law No. 9072 of 2003 in Cordoba province.

**Brazil:** Article 8 of Law 8.974 of 1995 on the Uses of Genetic Engineering Techniques and Release of Genetically Modified Organisms into the Environment expressly prohibits the genetic manipulation of human germinal cells and intervention *in vitro* human genetic material. Exemptions may apply to therapeutic purposes and the treatment of genetic diseases, subject to certain ethical considerations and prior governmental approval. After a thorough analysis of the law, the Brazilian Biosafety Technical Commission of the Ministry for Science and Technology issued two normative instructions in 1997 to clarify the intended ban on human reproductive cloning; specifically stating that genetic manipulation of human germinal cells includes the nuclear transference technique.

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**Canada:** Act Respecting Assisted Human Reproduction and Related Research (Assisted Human Reproduction Act) prohibiting reproductive and therapeutic cloning was adopted in March 2004. Article 5 states: "No person shall knowingly (a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device; (b) create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;(c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or fetus or transplant an embryo so created into a human being." However, the research on embryos will be controlled under regulations and a license which may open the way to conduct embryonic stem cell research with certain conditions such as using supernumerary embryos.

**Mexico:** The General Health Law of 7 May 1997 and its regulations in the field of research for health care provide articles which can be interpreted as implicitly prohibiting human cloning. For example, Article 100 of the law and Article 13 and 15 of the regulations state that the interest of human beings prevails over that of science; Article 319 of the law prohibit the trade of human organ, tissues and cells; Article 100 and 300 of the law, Article 14 and 36 of the regulations concerning the use of human organs, tissues and bodies, requires the express consent of the person involved for the research on human bodies, donation and transplant of organs; Article 330 of the law prohibits the use of embryonic tissues or fetus tissues for any purposes.

**Peru:** Article 7 of the General Health Law (No. 26842) of 1997 prohibits fertilization of human oocytes other than for procreation, as well as reproductive cloning of human beings. Peruvian Criminal Code Article 234 makes any person employing any genetic manipulation technique for purposes of cloning a human being punishable by imprisonment from six months up to eight years. These provisions constitute a sweeping and permanent ban of reproductive cloning. However, since the somatic cell nuclear transfer (SCNT) technique will not involve any fertilization of a human oocyte, the Law seems to leave therapeutic cloning legal.<sup>212</sup>

**United States:** In the United States there is no federal legislation prohibiting cloning for either reproductive or therapeutic purposes. However, under the 1996 Dickey-Wicker Amendment it is illegal to use federal funds to support research "in which human embryos are created, destroyed, discarded, or knowingly be subjected to risk of injury or death greater than allowed for research on fetuses *in utero* under 45 CFR 46.204 and 46.207, and subsection 498(b) of the Public Health Service Act." Moreover, the Dickey-Wicker Amendment defines a human embryo as "any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

<sup>&</sup>lt;sup>212</sup> See JOHN CHARLES KUNICH, *supra*, note 209, at 75

In late February 2003, the U.S. House of Representatives passed a bill named the Human Cloning Prohibition Act of 2003 (H.R. 234) that would ban human cloning for reproductive and therapeutic purposes. It would make it unlawful for anyone "to perform or attempt to perform human; to participate in an attempt to perform human cloning; or to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo." The bill would impose a prison sentence of up to 10 years for violators and fines beginning at \$1 million. This bill was almost identical to the Human Cloning Prohibition Act of 2001 (H.R. 2505) which was passed in the House in July 2001. Both of them were not acted upon by the Senate. Recently, the Human Cloning Prohibition Act of 2007 (H.R. 2560) was introduced on June 5, 2007 and defeated in the House. Republicans called it a "phony ban" that does not prohibit cloning but only the implantation of a clone into a woman.

At state level, at least eight states have passed laws explicitly prohibiting human reproductive cloning, five of which prohibit human cloning for any reason. At least 22 others have introduced bills that would outlaw the reproductive cloning of human beings.

#### 4. African Nations

**Egypt:** A draft law addressing human reproductive cloning practices is currently under consideration. In conformity with a report produced by Islamic Research Academy, Egyptian authorities have issued an opinion strictly prohibiting experimental research on human

reproductive cloning and allowing research into cloning of human tissues and cells for therapeutic purposes, as long as human rights and dignity are respected.

**South Africa:** The Law on Human Tissue of 1983 implicitly prohibits the cloning of human cells. Section 39A states: "Notwithstanding anything to the contrary contained in this Act or any other law, no provision of this Act shall be so construed as to permit genetic manipulation outside the human body of gametes or zygotes." In 1998, a bill calling for the prohibition of human cloning was submitted to Parliament. However, it was rejected by Parliament on the basis that the very same issue was to be addressed in the Draft National Health Bill which was scheduled to be tabled later that same year. At present, however, the bill is still awaiting review.

### 5. Oceania Nations

Australia: Section 192B of the Gene Technology Act of 2001 prohibits "cloning of human beings" subject to criminal sanctions. It defines "cloning of a whole human being" as "the use of technology for the purpose of producing, from one original, a duplicate or descendant that is, or duplicates or descendants that are, genetically identical to the original." Thus, the Act applies only to reproductive human cloning techniques. At the state level, Victoria, Western Australia and South Australia have incorporated the regulations set out in the Gene Technology Act of 2001 into their respective state laws.

Furthermore, the Prohibition of Human Cloning for Reproduction Act of 2002 and the Research Involving Human Embryos Act of 2002 received Royal Assent on 19 December 2002 following the historical split of the bill in September. The legislation prohibits certain unacceptable practices including human cloning and regulates certain uses of excess human embryos created through assisted reproductive technology (ART). The human cloning ban applies to the creation of cloned embryos for reproductive and related purposes, to attempts to implant such an embryo into a uterus, and to their import and export. Part 2, Division 1. Section 9 reads: "A person commits an offence if the person intentionally creates a human embryo clone. Section 10 states: "A person commits an offence if the person intentionally places a human embryo clone in the body of a human or the body of an animal." Section 11, Paragraphs (1) and (2) further prescribe that "A person commits an offence if the person intentionally imports a human embryo clone into Australia. A person commits an offence if the person intentionally exports a human embryo clone into Australia." All offences under this ban are punishable by up to 15 years' imprisonment.

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In 2005, the Legislation Review Committee (also referred to as the "Lockhart Review Committee") conducted an independent review of both the Research Involving Human Embryos Act and the Prohibition of Human Cloning Act in order to assess the existing regulatory framework in light of scientific progress and changes in community understanding and standards since 2002. One key recommendation made by the committee consists of changing the legal definition of the human embryo. A "human embryo" would then be considered a "discrete living entity" and defined as such when it is 14 days old and no sooner. Lifting the ban on therapeutic cloning, or somatic cell nuclear transfer (SCNT), under strict ethical and scientific regulation, was supported by the Committee in this review. However, reproductive cloning should remain banned. The Committee also recommends certain administrative improvements that will help increase regulatory flexibility in the licensing process and the provision of further support to the regulatory scheme by enhancing the National Health and Medical Research Council guidelines. The committee's reports were tabled in both Houses of Parliament and presented to the Council of Australian Governments on December 19, 2005.<sup>213</sup>

**New Zealand:** The Medicines (Restricted Biotechnical Procedures) Amendment Act 2002 provides temporary measures, pending the development of a comprehensive legislative scheme, to control the use of cloning procedures for reproductive purposes. Under this Act, a procedure such as reproductive cloning may not be authorized by the Minister of Health unless it satisfies the following conditions: (a) the conduct of the procedure or class of procedure does not pose an unacceptable risk to the health or safety of the public; (b) any risks posed by the conduct

<sup>&</sup>lt;sup>213</sup> See Genetics and Public Policy Center, *Research Involving Human Embryos Act and the Prohibition of Human Cloning Act*, in INTERNATIONAL LAW RESEARCH, at http://www.dnapolicy.org/policy.international.php?action =detail&laws\_id=11
of the procedure or class of procedure will be appropriately managed; (c) any ethical issues have been adequately addressed; (d) any cloning issues have been adequately addressed; (e) any spiritual issues have been adequately addressed.

Two bills aimed at regulating assisted human reproduction were introduced in 1996 (The Human Assisted Reproductive Technology Bill (HART) and in 1998 (The Assisted Human Reproduction Bill). However, given the rapid progress in cloning knowledge concerning assisted human reproduction, the Government has decided that updating is necessary and is currently developing a comprehensive framework for the regulation of human reproductive technologies. In 2001, the Government decided to amend the HART bill through a Supplementary Order Paper (SOP) referred to a select committee for public comment in May 2003. The Government's intent is for resulting legislation to be enacted in early 2004. This proposed legislation would provide a permanent legislative framework for human reproductive cloning, superseding the 2002 Act. The SOP prohibits cloning for reproductive purposes, but allows for therapeutic cloning, subject to further investigation and regulatory measures to be defined.

# **B.** Regional Level

## 1. European Region

At the European region, Paragraph 1.31 of the European Council Declaration on Banning the Cloning of Human Beings (ECDBCHB) of 1997 noted that "... [A]mong the most recent developments, cloning presents specific and very serious dangers." It further urged the Member States for their part "[T]o take all measures necessary to prohibit human cloning." The Council of Europe, therefore, established the succinctly named Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention). The document is a major framework for European nations to adopt as a minimum standard to protect human rights and dignity in medical research.<sup>214</sup> It also expressly forbids the creation of human embryos for research purposes.

The Convention was opened on 4 April 1997 for signature by the member States, the non-member States which have participated in its elaboration and by the European Community, and for accession by other non-member States. Articles 13 of the Convention provides: "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." Article 18 further states: "(1) Where the law allows research on

<sup>&</sup>lt;sup>214</sup> See Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, CETS No. 164, available at http://conventions.coe.int/Treaty/Commun/ListeTraites.asp?CM=8&CL=ENG

embryos *in vitro*, it shall ensure adequate protection of the embryo. (2) The creation of human embryos for research purposes is prohibited." The Convention has attracted the ratifications or accessions of twenty-two nations, and the signature of twelve nations.

In addition, if the national legislation of the member state permits research on embryo *in vitro*, it calls for adequate protection of the embryo. Because of the considerable ambiguity in the words used in the Convention, the Council of Europe adopted an Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings. The Additional Protocol was introduced for ratification on 12 January 1998 and came into force on 1 March 2001. This Additional Protocol described cloning as a valuable and ethical biomedical technique, and it acknowledged differences of opinion about the cloning of undifferentiated cells of embryonic origin.<sup>215</sup>

Article 1 of the Additional Protocol states: "(1) Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited. (2) For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene."<sup>216</sup> It prohibits human

<sup>&</sup>lt;sup>215</sup> See UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION (UNESCO), ETHICAL ISSUES HUMAN CLONING, updated in 2005, at http://unesdoc.unesco.org/images/0013/001359/135928e.pdf

<sup>&</sup>lt;sup>216</sup> See Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, *supra*, note 200, at CETS No. 168

cloning generically but not any particular cloning technique such as somatic cell nuclear transfer (SCNT) or embryo splitting.<sup>217</sup> Thus, while the Additional Protocol did not take a specific stand on the cloning of cells for research purposes, it prohibited any deliberate cloning of human beings as a threat to human dignity. This Additional Protocol became the first biding international legal document concerning the cloning of humans and has been ratified by Croatia, Cyprus, Czech Republic, Estonia, Georgia, Greece, Hungary, Lithuania, Republic of Moldova, Portugal, Romania, Slovakia, Slovenia and Spain.<sup>218</sup> These deliberations and the gravity of the issue encouraged the United Nations General Assembly to commence discussion in 2001 following a France-German initiative to draft a convention against the reproductive cloning of human beings, as the possible concerns framework to regulate such phenomena.<sup>219</sup>

Furthermore, Article 3(2) of the European Union Charter of Fundamental Rights (EUCFR), entitled "Rights to the Integrity of the Person," also insists that "In the field of biology and medicine, the following must be respected in particular: -- the prohibition of eugenic practices, in particular those aiming at the selection of persons, the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive

<sup>&</sup>lt;sup>217</sup> See JOHN CHARLES KUNICH, *supra*, note 209, at 65-67

<sup>&</sup>lt;sup>218</sup> See Heidi Forster, Emily Ramsey, Legal Perspectives on Cloning of Human Beings, 32 VAL. U. L. REV. 433, 454 (1998)

<sup>&</sup>lt;sup>219</sup> See UNECO, supra, note 215

cloning of human beings.<sup>220</sup> Most importantly, the European Union (EU) disburses some US\$5 to 6 billion every seven years for biomedical and health-related research, and sets policies on the use of these funds. Under its current plan, which runs from 2007 to 2013, these funds cannot be used for research that involves human reproductive cloning, inheritable genetic modification, the creation of human embryos solely for research purposes, or the destruction of human embryos. Although the European treaties, which deal with more general issues, are only applicable in EU's twenty-seven member states and the European countries that ratified them, this situation undoubtedly offers an appropriate opportunity to reflect on the possibility of a universal consensus instrument on biotech development and bioethical concerns.

## 2. African Region

At the African region, the African Union (AU) is an intergovernmental organization consisting of most African nations. At its 1996 Assembly of Heads of State, the AU (then called the Organization of African Unity) approved a Resolution on Bioethics that affirmed "the inviolability of the human body and the genetic heritage of the human species" and called for "supervision of research facilities to obviate selective eugenic by-products, particularly those relating to sex considerations."

<sup>&</sup>lt;sup>220</sup> See Official Journal (O.J.) of the European Communities, C 346/1 (18 December 2000), also available at http://www.europarl.europa.eu/charter/pdf/text\_en.pdf

In 1996 Yaounde Summit, Cameroon introduced an item relating to Bioethics in Africa and the Summit endorsed the Constitution of an African Bioethics Association. However, the need for African ethical guidelines covering all issues in the field of bioethics is increasingly felt by specialists and decision-makers. In this respect, both the Declaration on Science and the Use of Scientific Knowledge and the Science Agenda – Framework for Action were adopted in 1999 in Budapest. These documents highlighted the ethical dimension of the present-day development of science and technology.

In respect of bioethical considerations in human cloning technology, at the July 2004 Addis Ababa Summit, South Africa introduced an item on the Cloning of Human Beings. After taking into account the factors regarding (1) the responsible exercise of scientific research and invention to improve the condition of human beings, (2) what is permissible with regard to this exercise, and (3) alternative frameworks for arriving at a broad consensus concerning important issues, the Executive Council of the Summit voted for the Decision EX.CL/Dec.160(v) on the Development of an African Position on the International Convention Against the Reproductive Cloning of the Human Being, by which it was requested that the issue of human reproductive cloning should be looked into thoroughly.<sup>221</sup> As a result, Africa develops and adopts a Common Position together with a Framework in the form of regional Legal Instrument to deal with all

<sup>&</sup>lt;sup>221</sup> See African Union, Issue of Human Cloning within the Overall Context of a Bioethics Programme: Priorities and Perspectives for Africa, 12/8/2004, available at http://african-union-news.newslib.com/story/1589-1106643/

aspects relating to Bioethics in Scientific Research and Human Life, including the issue of Reproductive Cloning of the Human Beings and the International Convention which is being developed accordingly.<sup>222</sup>

# **C. International Level**

The world has been active in anti-cloning legislation for years. From the viewpoint of international community, some international bodies such as the United Nations Education, Scientific and Cultural Organization (UNESCO) have made significant efforts over the last few years to reach an international consensus on some basic principles relating to today's life science and biomedical development. The recent regulatory activity on human rights and biomedicine of both bodies mentioned above was preceded and inspired by the initiative of various international organizations. The World Health Organization (WHO), the World Medical Association (WMA, which also developed Helsinki Declaration on Biomedical Research of 1964), and the Council for International Organizations of Medical Sciences (CIOMS, which prepared and revised the International Ethical Guidelines for Biomedical Research Involving Human Subjects of 1992) are perhaps the most important examples.<sup>223</sup> For instance, the World Health Assembly (WHA)

<sup>&</sup>lt;sup>222</sup> Id.

<sup>&</sup>lt;sup>223</sup> See Robert Andorno, *Biomedicine and International Human Rights Law: In Search of A Global Consensus*, 80 BULLETIN OF THE WORLD HEALTH ORGANIZATION, No.12 (Geneva, 2002); also available at www.scielosp.org/ scielo.php?script=sci\_arttext&pid=S0042-96862002001200010&lng=es&nrm=iso&tlng=en

of WHO affirmed in its resolution WHA 50.37 of 1997 and resolution WHA 51.10 of 1998 that "cloning for the replication of human individuals is ethically unacceptable and contrary to human dignity and integrity."

At present, there are different international instruments and provisions dealing with either reproductive or therapeutic human cloning technology under international human rights law regime. The Universal Declaration on the Human Genome and Human Rights (UDHGHR) was adopted by the 29<sup>th</sup> General Conference of the United Nations Educational. Scientific and Cultural Organization (UNESCO) on 11 November 1997 and endorsed by the General Assembly of the United Nations by its resolution 53/152 of 9 December 1998. It was a landmark document that took its place in the growing discussion of human cloning and also the first international instrument to condemn human reproductive cloning as a practice against human dignity.<sup>224</sup> Although it is a non-binding resolution focusing exclusively on genetics related matters, it is deemed to serve as a major source of international soft laws and has indirectly influenced general knowledge and image on human cloning of many national governmental authorities. The Declaration expressly banned the reproductive cloning of human beings. Its Article 11 of the Declaration clearly prescribes:

[P]ractices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected.<sup>225</sup>

The World Health Organization (WHO) and its governing body, the World Health Assembly (WHA), are specialized agencies of the United Nations that address issues of international public health. In 1997 the WHO called for a global ban on human reproductive cloning. In 1999 a Consultation on Ethical Issues in Genetics, Cloning and Biotechnology was held to help assess future directions for the WHO. The draft guidelines prepared as part of this consultation, Medical Genetics and Biotechnology: Implications for Public Health, called for a global ban on inheritable genetic modification. In September 2001 the WHO convened a meeting to review and assess "recent technical developments in medically assisted procreation and their ethical and social implications." In February 2002 the WHO repeated its opposition to human reproductive cloning and cautioned against banning cloning techniques for medical research. In October 2002 the WHO established a Department of Ethics, Equity, Trade, and Human Rights to coordinate activities addressing bioethical issues.

<sup>&</sup>lt;sup>225</sup> See Universal Declaration on the Human Genome and Human Rights, Article 11

In December 2001, France and Germany proposed that the United Nations develop an international convention against the reproductive cloning of human beings and requested the United Nations General Assembly to ban human reproductive cloning. The primary impetus behind the initiative was apparently a concern that those threatening to clone a human being would engage in venue shopping, looking for a nation that had not yet legally banned reproductive cloning. They suggested that because the threat of human reproductive cloning was imminent, a convention to deal with this issue be developed immediately. An international convention against such cloning, if approved by the United Nations, would at least announce an international moral consensus against reproductive cloning, and would ban it in nations that ratified the convention. They further suggested that this be followed by a separate convention that dealt with therapeutic cloning or research on stem cells.

Under its resolution 56/93 of 12 December 2001, co-sponsored by 50 states, an Ad Hoc Committee on International Convention against the Reproductive Cloning of Human Beings highly supported by UNESCO was established by the General Assembly of the United Nations to consider the magnification of such a convention. This initiative was a direct response to the request of the French and German governments to the United Nations to draw up a worldwide ban on broader application of human cloning technology. The first meeting of the Committee took place in New York from 25 February to 1 March 2002, the second from 23 to 27 September. A number of UNESCO documents in the bioethics field were made available to Committee members. At the same time, the positions of United Nations member states pointed to a divide between two different approaches: a broad-scope ban on both reproductive and research cloning and a restricted-scope ban on reproductive cloning while research cloning to be addressed separately. The convention concluded in 2003, but the central issues on whether it should ban only reproductive cloning or whether it should also include the creation of cloned human embryos for therapeutic purposes still remained unresolved.

In November of 2004, the Sixth Committee of General Assembly of the United Nations failed to reach its decision on an international convention against human cloning proposed by Costa Rica for the purpose of universally banning any research, experiment, development or application of any technique aimed at human cloning. In February of 2005, a Working Group established by the General Assembly of the United Nations finalized a draft proposed by Honduras for the United Nations Declaration on Human Cloning. Despite support for the continued consideration of the topic and attempts based on various proposals to move forward, the Working Group was unable to reach consensus on the mandate and scope of a future convention. The discussions continued to reveal a deviation of views among delegations. There was a clear division between those delegations who were in favor of a convention prohibiting all forms of human cloning and those delegations who favored a more restrictive approach that would call for a convention prohibiting reproductive cloning of humans, but would also allow for other forms of cloning such as therapeutic cloning under a strict regulatory regime.

Following the recommendation by the Sixth Committee, the United Nations General Assembly on 8 March 2005 voted in favor of the United Nations Declaration on Human Cloning (UNDHC) proposed by the Sixth Committee, by its resolution 59/280 and by a vote of eighty-four to thirty-four with thirty-seven abstentions.<sup>226</sup> In the Declaration, Paragraphs (a) through (e) of the Declaration state:

(a) Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences; (b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and protection of human life; (c) Member States are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity; (d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences; (e) Member States are called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d).

As a matter of law, the Declaration is only a non-binding statement urging member nations to individually adopt legislation prohibiting all forms of human cloning that are incompatible with human dignity and the protection of human life. According to this

<sup>&</sup>lt;sup>226</sup> See United Nations Declaration on Human Cloning, Paragraphs (a)-(e)

international instrument, if any reproductive, therapeutic, or experimental human cloning violates human dignity or infringes on human life, it shall be overly prohibited. As a result, the reactions to human cloning in the international community reflect less legal but more ethical concerns.<sup>227</sup>

Not surprisingly, most Roman Catholic nations endorsed the passage of the Declaration, citing ethical justifications. Nations including South Korea, Belgium, and the United Kingdom, which have supported allowing therapeutic cloning research, opposed the Declaration and do not intend to change their current policies. Nations of the Organization of the Islamic Conference dominantly abstained from the vote. However, many nations voiced opposition to the Declaration, not because of some ethical or religious concerns but the vagueness of the use of the term "human life," feeling that varying interpretations could allow for a future convention limiting the rights of sovereign states supporting therapeutic research or completely banning all cloning research. Canada voiced a concern that the ambiguity of the terminology could be diluting the nation's current policies.

On the contrary, proponents of the Declaration see it as a monumental step towards a universal ban on all forms of human cloning without any exceptions in the near future. Although it is difficult to find a consensus on this topic with such varied opinions, the Declaration has at

<sup>&</sup>lt;sup>227</sup> See Tade Matthias Spranger, *Ethical Aspects of Patenting Human Genotypes According to EC Biotechnology Directive*, 31 INTERNATIONAL REVIEW OF INDUSTRIAL PROPERTY AND COPYRIGHT LAW 373, 380 (2000)

least expressed an attempt to reach a universal agreement that the balance between scientific development of human cloning and the rights of humanity is the common goal among the member nations of the United Nations.<sup>228</sup>

Obviously, the rationale of the international instruments and provisions mentioned above is mainly based on the idea of protection of human dignity. Since there may be different views on what constitutes human dignity that deserves to be fully respected, what kind of human dignity can be technically protected by secular legal systems, and whose dignity has actually already be infringed in the field of biomedicine, there is no doubt that a variety of opinions may inevitably exist among different nations or areas as to the ethical and scientific value of human cloning technology.

## **D.** Other Infrastructural Level

The Group of Eight (G-8) is an international forum for the governments of Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States. It convenes annual summits to consider issues of common concern, typically of an economic or military nature. At its June 1997 23<sup>rd</sup> summit in Denver, Colorado, the G-8 called for a worldwide ban on human reproductive cloning. According to the Final Communiqué of the Denver Summit of

<sup>&</sup>lt;sup>228</sup> See *General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37*, UN News on 3 August 2005, at http://www.un.org/News/Press/docs/2005/ga10333.doc.htm

the Eight, the leaders of the G-8 nations agreed "[O]n the need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child."<sup>229</sup>

# III. Regulatory Consensus Regarding Human Cloning Technology

## A. Human Dignity Approach

#### 1. Imago Dei

Human dignity refers to the intrinsic worth or value that inheres in every human being. Consequently, human beings are valuable in themselves, simply as human beings. Based on the Catholic and some other Christian perspectives, the source of human dignity is rooted in the concept of *Imago Dei* (Image of God), in Christ's redemption, and in human ultimate destiny of union with God the Creator. Human dignity therefore goes above any social order as the basis for rights and is neither granted by society nor can it be justifiably violated by society. In addition, because the religious tradition of sanctity of human life in many perspectives emphasizes the integral nature of human body and holistic spirit, the human life should be treated with great reverence and respect.

<sup>&</sup>lt;sup>229</sup> See COMMUNIQUÉ OF GROUP 8 DENVER SUMMIT – 1997, available at http://www.g8.fr/evian/ english/navigation/g8\_documents/archives\_from\_previous\_summits/denver\_summit\_-\_1997/communique.html

Human cloning is the scientific technique by which a human being may be asexually generated. The beginning of a new member of the human species may occur when a one-cell embryo is produced by fusing the nucleus of a somatic cell with an enucleated ovum. It is human because of its human genetic material, and it is life because it is a self-developing entity. Thus, no matter which purposes human cloning can be attempted, a real human life is artificially created in a new zygote by this process.

Technically, a human embryo is an actual human being who deserves to be treated as equal dignity as any other human beings. The crucial point is simple to state: a human being, as a unique, individual, rational being, is from the moment of its conception possessed of an inherent dignity and worth that is immeasurable.<sup>230</sup> The words of *Donum Vitae* stated:

[T]hus the fruit of human generation, from the first moment of its existence, that is to say from the moment the zygote has formed, demands the unconditional respect that is morally due to the human being in his bodily and spiritual totality. The human being is to be respected and treated as a person from the moment of conception; and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life.<sup>231</sup>

<sup>&</sup>lt;sup>230</sup> See John F. Morris, *Cloning and Human Dignity*, 29.2 ETHICS AND MEDICS (February 2004), also available at http://www.lifeissues.net/writers/mor/mor 01cloningdignity.html#b3

<sup>&</sup>lt;sup>231</sup> See Congregation for the Doctrine of the Faith, Donum Vitae, Instruction on Life in Its Origin and on the Dignity of Procreation, in 1987 UNITED STATES CATHOLIC CONFERENCE, WASHINGTON, D.C., I, n. 1

The ethical implication here is that each unique human embryo should be treated as an end or purpose, not as a means or object. If cloning is purposed with the aim of making a human baby, the dignity of the cloned human being has been inherently threatened from the moment of conception because other human beings and technological powers have exercised undisputed dominion over the duration of this human being's life or his or her value for existence. On the other hand, if cloning is pursued to accomplish biomedical researches or produce stem cells, cloning a human embryo would constitute a deliberate, systemic destruction of nascent human life in the name of potential therapy or scientific discovery for some other human beings. This prospect may be morally and ethically evil in many considerations. Therefore, it is not a worthy way for humans to bring other humans into the world without any persuasive cause or equitable justification.

#### 2. Universal Declaration of Human Rights (UDHR)

Various international instruments acknowledge that the dignity of the human being is at the center of international law. Regardless of the objective for which it was done, human cloning conflicts with the international legal norms that protect human dignity. In addition, the safekeeping of present and succeeding generations of human beings is critical to the work of the United Nations. Article 3 of the Universal Declaration of Human Rights (UDHR) further guarantees "everyone's" right to life. In this regard, facilitating the formation of human beings who are destined for destruction, the intentional destruction of cloned human beings once the particular research goal is accomplished, relegating any human being to an existence of either involuntary servitude or slavery, and being submitted to involuntary medical and biological experimentation on human beings are apparently repugnant to the understanding of human dignity in the international community and thus impermissible.<sup>232</sup>

# **B.** Human Rights Approach

## 1. Natural Rights

Human rights refer to basic rights that belong to an individual as a consequence of being human. The term came into being widely recognized after World War II, replacing the earlier phrase "natural rights," which had been associated with the Greco-Roman concept of natural law since the end of the middle ages. The protection of human dignity has been treated as the foundation of human rights. As understood today, human rights relate to a wide variety of values and capabilities reflecting the diversity of human circumstances and history. They are conceived of as universal, applying to all human beings everywhere, and as fundamental, referring to essential or basic human needs.

<sup>&</sup>lt;sup>232</sup> See Vatican's Mission to the United Nations, *The Views of the Holy See on Human Cloning*, February 2003, at http://www.lifeissues.net/writers/doc/doc\_11humancloning.html

Article 1 of the Universal Declaration of Human Rights (UDHR) states: "All human beings are born free and equal in dignity and rights..." Following the idea set up in this Article, the concept of human rights can be realized in at least some succeeding aspects. First, human rights seek to ensure all human lives as dignity as possible. Second, human rights are universally applicable to all people around the world, regardless of their race, color, origin, gender, religion, language, legitimacy, property and other status. Third, human rights treat people as equal as possible. Each State is expected to provide equal and effective human rights protections fitted to its all people. Fourth, human rights protections are not bounded by the frontier of any State. Each State has a responsibility to respect and promote human rights recognized by the international community. Since human rights encompass the fundamental principles of humanity, some rights, such as right to life, freedom from slavery, and freedom from torture, are absolute in nature and cannot be interfered with under any circumstances.<sup>233</sup>

Since the adoption of the Universal Declaration of Human Rights (UDHR) in 1948, many treaties and agreements for the protection of human rights have been concluded through the patronage of the United Nations, and several regional systems of human rights law have also been established. The rights and freedoms which have come to be commonly described in

<sup>&</sup>lt;sup>233</sup> See International Federation of Red Cross and Red Crescent Societies and Fran Dois-Xavier Bagnoud Center for Health and Human Rights, *Human Rights: An Introduction*, in HEALTH AND HUMAN RIGHTS 21-23 (Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, George J. Annas eds., Routledge, 1999)

human rights documents as human rights include two categories: civil and political rights which must be guaranteed immediately, such as the right to life, liberty, and security of persons, recognized in the International Covenant on Civil and Political Rights (ICCPR); economic, social, and cultural rights which should be progressively realized, including the rights to the highest attainable standard of health, to work, to social security, and to enjoy the benefits of scientific progress and its application, recognized in the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>234</sup>

## 2. International Covenant on Civil and Political Rights (ICCPR)

Due to the evidence that dignity only was unable to provide a concrete solution to most challenges raised by scientific advances, human rights today have a highly vigorous role to play in the area of bio-technology. Article 23 (2) of the International Covenant on Civil and Political Rights (ICCPR) states: "The right of men and women of marriageable age to marry and to found a family shall be recognized." Furthermore, Article 16 (1)(e) of the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) also reads: "States Parties shall take all appropriate measures to eliminate discrimination against women in all matters relating to marriage and family relations and in particular shall ensure, on a basis of

<sup>&</sup>lt;sup>234</sup> See The International Covenant on Civil and Political Rights (ICCPR), 16 December 1966, 993 U.N.T.S. 171; and The International Covenant on Economic, Social and Cultural Rights (ICESCR), 16 December 1966, 993 U.N.T.S. 3

equality of men and women: ...(e) The same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights...<sup>235</sup>

Thus, reproductive rights embrace certain human rights that are already recognized in international human rights documents. These rights rest on the recognition of the basic right of all couples and individuals to decide freely and responsibly the number, spacing and timing of their children and to have the information and means to do so, and the right to attain the highest standard of sexual and reproductive health.<sup>236</sup> It is well known that the *in vitro* fertilization (IVF) through assisted reproductive technologies (ARTs) has long been widely recognized as an acceptable means of implementing this right. Would a similar permissive position extend to human cloning technology for reproductive purpose as a means of realizing the human right to found a family?

#### 3. International Covenant on Economic, Social and Cultural Right (ICESCR)

In addition, Article 12 of the International Covenant on Economic, Social and Cultural Right (ICESCR) recognizes "[T]he right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Article 15 (1) (b) also recognizes "[T]he right of

 <sup>&</sup>lt;sup>235</sup> See Convention on te Elimination of All Forms of Discrimination Against Women (CEDAW), Article 16(1)(e)
<sup>236</sup> See Programme of Action of the International Conference on Population and Development (ICPD) (Cairo, 5-13
September 1994), A/CONF.171/13, Para. 7.3 (18 October 1994)

everyone to enjoy the benefits of scientific progress and its applications." In its General Comment, the Committee on Economic, Social and Cultural Rights (CESCR) analysis the right to health recognized in international human rights documents as "[T]he right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, nonconsensual medical treatment and experimentation." The CESCR lists four "interrelated and essential elements" of services in relation to the right to health, i.e., accessibility, affordability, appropriateness, and quality of care.<sup>237</sup> Would the human cloning technology for therapeutic purpose contribute appropriate opportunities to improve human health and thus be permissible and supportable in this regard under the eyes of the international human rights instruments?

#### 4. Universal Declaration on the Human Genome and Human Rights (UDHGHR)

The human rights strategy adopted by recent international legal instruments relating to human biotechnology seems to be the most appropriate way to manage bioethical issues on the field of scientific techniques as human cloning technology here. Concerning about that human cloning has already found expression in international human rights instruments, the 1997 Universal Declaration on the Human Genome and Human Rights (UDHGHR) recognizes that genetics research could have vast potential for improving the health of mankind, but it also

<sup>&</sup>lt;sup>237</sup> See Stephen P. Marks, Human Rights Assumptions of Restrictive and Permissive Approaches to Human Reproductive Cloning, 6.1 HEALTH AND HUMAN RIGHT 81, 92-93 (2002)

emphasizes the need to fully respect human dignity, freedom, and human rights. Article 11 of the Declaration states: "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted."<sup>238</sup> Under the regime of human rights jurisprudence, there is a need to undertake serious and detailed human rights analysis of the issues involved in human cloning technology for reproductive purpose. However, human cloning technology for therapeutic purpose may be expected to lead to significant health products. In this situation, the concern should be focus on the exploitation of women as egg donors and the need to protect women participating in research from violation of their human rights and dignity.<sup>239</sup>

## C. Fundamental Rights Approach

#### 1. Historical Foundation and Longstanding Tradition

The term of fundamental rights is a content of national law under which certain human rights are either explicitly or implicitly enshrined and codified in the domestic constitutional or fundamental law. Although many fundamental rights are also more widely considered to be human rights, the classification of a right as fundamental invokes specific legal scrutiny

 <sup>&</sup>lt;sup>238</sup> See UNESCO, Universal Declaration on the Human Genome and Human Rights (UDHGHR), 1997, Article 11
<sup>239</sup> See Carmel Shalev, *Human Cloning and Human Rights: A Commentary*, 6.1 HEALTH AND HUMAN RIGHTS 137
(2002)

performed by the courts to determine the carefully constrained conditions under which the State and its governments may impose limitations on these rights.

Whether rights are to be considered fundamental and carefully guaranteed by the constitution can be decided by examining whether those rights are the historical foundations in the nation and whether their protections are parts of a longstanding tradition in the society. The State may not restrict people's fundamental rights unless the restricting law serves a compelling state interest and is narrowly tailored to achieve that purpose and is the least restrictive means to its people. The reviewing court must review the law that infringes on a fundamental right under a standard of strict scrutiny.

#### 2. Strict Scrutiny

Recognition on whether there is a fundamental right to clone either for reproductive or for therapeutic purposes is critical for a reviewing court to decide whether a strict scrutiny should be applied when the human cloning technology related cases are reviewed before her. A fundamental right could be enumerated by the constitution of a State, or implied in the spirit and structure of the constitution and be substantively found by the reviewing court. However, simply recognizing that cloning technology may be helpful to realize some long-existing fundamental rights, such as right to procreation or right to health, cannot lead the reviewing court to conclude that people's right to clone is fundamental and ought to be ensured by the constitution of a State. Determination of whether the right to clone for reproductive or therapeutic purposes is fundamental or whether an anti-cloning law ought to be established is a sovereignty matter belonged to each State. If a State, based on a decision made through its political or judicial process, would like to find the right to clone is a new fundamental right, the outcome would require the State to demonstrate a compelling interest to justify any infringement on that right. For example, the State could insist that a law to ban the newly-developed human cloning technology is necessary to prevent catastrophic disorders in the society if the technology is currently uncertain, dangerous, or unsafe to any existing or prospect human beings. Different concerns may be visualized and evaluated among different sovereignty nations.

#### **D.** Humane Concerns Approach

#### 1. Humane Society

Humane concerns refer to the quality of compassion or consideration for others. Humane in early use meant civil, courteous or obliging in the treatment of humans and animals. In modern times, it is characterized by sympathy with or consideration, tenderness, compassion, and benevolence for others, especially for the suffering or distressed. Not all humane concerns are regulated by law or other legal instruments because they are mandated by some superior commitments which are integrated with the consciousness of a society at large. The fact that stem cells research involved in human cloning technology commits great torture and mass destruction on human embryos used in the process requires the need of humane concerns for those embryos.

From 2001, Bush Administration of the United States has established a policy model regarding humane concerns for the human embryos that could advance stem cell science without destroying human life. In the White House Report "Advancing Stem Cell Science without Destroying Human Life, its executive summary states:

[I]n 2001, President Bush established a policy on stem cell research that promotes scientific progress while respecting ethical boundaries. This policy is based on the President's firm belief that science and ethics need not be at odds, and that a balance can be struck between the natural desire for rapid scientific progress and the demands of conscience. Drawing careful distinctions between practices that avoid ongoing destruction of nascent human life and those that do not, the President's policy has allowed stem cell research to advance in rapid and promising ways—as the pages that follow will illustrate—without sacrificing the inherent dignity and matchless value of every human life.

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[I]n sum, it increasingly appears that the qualities researchers value in embryonic cells may also exist in other stem cells that are easier to procure, more stable to grow, safer to use in therapies, and free of the ethical violations of embryo destruction. There is a gathering consensus among experts, thanks to technical

advances, that today's heated controversies over research that harms embryos could fade in the future.

The dramatic advances in stem cell research since 2001 are evidence that the President's balanced policy is working. Scientists have shown they have the ingenuity and skill to pursue the potential benefits of embryonic stem cell research without endangering nascent human life in the process. In supporting these alternative approaches while maintaining longstanding bioethical guardrails which protect life and dignity, federal science-research funding can stay true to the ideals of a humane society.<sup>240</sup>

## 2. Sanctity of Human Life

The ethical concerns and political debates revolve about the fact that embryonic stem cell research inevitably requires mass destruction of human embryos used in the process. Opponents argue that embryos are human life, and thus should be protected as human beings, while proponents insist that these human embryos are created only for scientific inquiry purpose and most of them will be destroyed in laboratory for public good anyway.

However, it is no doubt that human embryonic stem cells possess the potential to differentiate all type of specialized cells and have the capability of becoming a real and full human. They are bequeathing from nature not only the force to develop but also the sanctity of human life. Therefore, as a civilized humane society, when it actively participates in creating a

<sup>&</sup>lt;sup>240</sup> See Domestic Policy Council, *Executive Summary*, in ADVANCING STEM CELL SCIENCE WITHOUT DESTROYING HUMAN LIFE 1-2 (The White House, April 2007)

future technology to promote the levels of human prosperity and well-being, a humane concern that could certainly sympathize with a scientific breakthrough which might have the most likelihood to save more human life should also be cautiously considered.

# IV. Conclusion

Until recent years, there were few ethical or legal discussions about human cloning since the scientific consensus was that such a procedure was not biologically possible. However, with the appearance of Dolly the sheep, the situation has dramatically changed. Although it now seems more likely that human cloning will become feasible, the everyday application of this technology may still be impractical today. To firmly safeguard the human rights and strictly preserve the value of human dignity from the potential hazards and risks of this new life science technology, it is worth of studying and evaluating, from ethical to legal perspectives, the advantage and influence of human cloning techniques and procedure before the practice comes into widespread use.

Human cloning technology offers remarkable insight into the power of creation that humanity has taken into its fold. Humans are moving ever closer to a posture of making babies, rather than having babies.<sup>241</sup> Based on current international consensus mentioned above, it seems that the majority of member nations in the United Nations are not inclined to give permission to such evolutionary techniques as human cloning in any sense. Nevertheless, some scientists have eagerly explained that human cloning is expected to result in several miraculous medical breakthroughs. Therefore, the anti-cloning law may underestimate possible benefits and overstate feared risks of the human cloning technique.

As mentioned before, the reactions of international community to human cloning involving human somatic cell nuclear transfer (SCNT) may reflect an ethical rather a legal dominated view. It appears that the majority is opposed to the cloning of human beings, especially reproductive human cloning technology. However, opinions and ideas may change along with more convincing and persuasive theory and experience. The human rights strategy adopted by recent international legal instruments relating to the field of biomedicine seems to be the most appropriate way to manage bioethical issues from a global perspective.

However, the ambiguous meaning of "human dignity" and "human life" described in the international instruments and provisions relating to human cloning should be redefined in a sense associated with current life science. Practically highlighting the separation of law and ethics is important for international bodies to impartially deal with such a prestigious fruit of modern life

<sup>&</sup>lt;sup>241</sup> See Glenn McGee, *Primer on Ethics and Human Cloning*, Published online February 2001, at www.lib.msuedu/skendall/cloning/ethics.htm

science technology. Any blending of ethical and legal issues will inevitably result in exceptional risks for legal clarity and certainty.

Furthermore, every country and the international community as a whole should balance the welfare of human beings with the importance of public interests when judging in favor or against human cloning. Safety of the mother and the cloned child should be a significant concern before any solid decisions on the development of any forms of human cloning can be determined. It may be proper to ban human cloning technology not only for the ethical issues, but also on the concern of safety.

If there is overwhelming evidence showing that human cloning technology is effective and the procedure is safe, then that will be the right time for the international community to convene again to consider a global consensus mechanism, without ignorance or infringement of human dignity and human rights, to jointly and cooperatively explore and exploit this novel legacy of humanity. Adopting an instrument which codify the moral, ethical, legal, social and cultural dimensions of the medical and life science as well as the technologies associated with them will thus be expected.

# **Conclusion and Recommendations**

# I. Fundamental Norms to Oversee Current Human Cloning Technology

Contemporary development of human cloning technology has to be seriously taken into account at national, regional, and international levels. Religious and moral imperatives may provide appropriate conscience duties to the community which engages in this novel life science technology, however, some generally-bound regulatory norms or principles of law may still be indispensable to efficiently oversee the advancement and evolution of human cloning technology in the near future.

Although different sovereign States may have a variety of notion ordinary to their national or regional legal systems, certain general norms, e.g., principles of due process of law, equal protection of law, proportionality, equity, etc, that are so fundamental and can be found in virtually every civilized legal system may be commonly acceptable as minimum standards to regulate current human cloning technology by almost all of the international community and, therefore, can be properly and competently applied to this scientific area. **Principle of Due Process of Law**: Principle of due process protects the depravation of a person's life, liberty, or property without due process of law, especially applies to the constitutionally safeguard of person's fundamental rights. These rights include the right to privacy, procreate, raise child, and keep the family together which could be realized by the support of human cloning techniques for reproductive purposes. On the other hand, these rights also include the right to health, care, healing, and enjoy a healthy life which could be sustained by the aid of human cloning techniques for experiment or therapeutic purposes. Once it is determined that those fundamental interests have been deprived but for lack of sufficient facilities to provide a full-scared human cloning process, the due process may be applied by the judiciary to review the governmental actions in question with a level of strict scrutiny.

Principle of Equal Protection of Law: Principle of equal protection guarantees that persons with similar situations are treated equally. Equal protection is triggered when a governmental action discriminately affects the rights or interests of some vulnerable persons or specifically classified groups, such as minority, women, children, the poor class, the indigenous persons or the aboriginal peoples, etc. In this analysis, where an anti-cloning law which systematically bans the existence, development, employment, or support of any kind of human cloning techniques without a compelling governmental purpose, and with respect to the activity, the law has substantially abridged an infertile woman some practicable options to realize her right to procreate, it can be subject to the principle of equal protection of law and may be reviewed by the judiciary with a level of intermediate or strict scrutiny.

**Principle of Proportionality**: principle of proportionality ensures the exercise of governmental power is limited to what is necessary to achieve the objectives of the government.<sup>242</sup> More specifically, the principle of proportionality means that any means employed by the government that may affect rights or interests of the people must be (1) appropriate for accomplishing the objectives; (2) necessary for achieving the objectives, i.e. it is the least restrictive means to achieve the objectives; and (3) reasonable, i.e. the person concerned can reasonably be expected to accept the means in question. A violation of this principle occurs when any one of those requisites mentioned above is dissatisfied.

As regards the application of this principle in a governmental action relating to human cloning, it may be considered lawful only if it is appropriate, necessary, and reasonable. Even more, the necessary requisite would be the most important issue with the first priority to be anatomized by the reviewing court. For example in a scenario that in order to achieve the governmental objective of sustaining morality, safe, health, and welfare of the people, the government promulgates a legislation which prohibits both reproductive and therapeutic human cloning techniques. However, many scientists have sufficient evidence to testify that adult or

<sup>&</sup>lt;sup>242</sup> See "Principle of Proportionality," EUROPA GLOSSARY, available at http://europa.eu/scadplus/glossary/ proportionality\_en.htm

somatic stem cells, which derive not from embryos or fetuses but from sources such as bone marrow, the umbilical cord or even from tissues of a grown individual, could be valuable in curing certain serious diseases and genetic disorders. Insomuch as that the legislation in question may be invalidated on its face for violation of the necessary requisite of the principle of proportionality because there is at least one less severe means of achieving the objective, e.g., prohibits human cloning techniques for reproductive purposes only.

**Principle of Equity:** Principle of equity is profoundly recognized by judges and legal scholars in both common law and civil law systems. It encompasses the ideals of fairness and equality explicit or implicit mandate to the conscience of humanity. When a judge believes that the law as a whole is limited or inflexible and cannot provide ultimate justice in a specific case or controversy, he or she may apply principle of equity to modify or supplement the rules of the law.

The equitable principle established by judicial discretion can form some parts of international law and may also be applied by the International Court of Justice (ICJ), in accordance with Article 38(1) (c) and Article 38 (2) of the Statue of the International Court of Justice which states: "The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply... c. the general principles of law recognized

by civilized nations..." "This provision shall not prejudice the power of the Court to decide a case *ex aequo et bono* (equal and good), if the parties agree thereto."<sup>243</sup>

In consideration of applying principle of equity to disputes concerning human cloning matters, it must be ascertained that there is no adequate rules of the law to govern and decide. For example, the question of whether informed consents on the use, storage and disposal of cloned embryos and fetuses from both sides of a couple should be obtained by the cloning facility before starting a somatic cell nuclear transfer (SCNT) process is matter to the case before the court, the judge should consider not only the rules and precedents governing informed consents obtained from the patients or clients at similar circumstances such as medical treatments or reproductive assisted processes, but also the value and moral status of the life possessed by the cloned embryos and fetuses. Since the law may only be competent to rule over matters involving the real human persons, the principle of equity may instead provide the prospect human persons with potential human life more thoughtful and respectful concerns and most conscious and philosophical regards.

# II. Effective Instruments to Safeguard Humanity in the Cloning Age

<sup>&</sup>lt;sup>243</sup> See MARK W. JANIS, AN INTRODUCTION TO INTERNATIONAL LAW, 67-75 (Aspen Publishers, 4<sup>th</sup> ed., 2003); also see the Statute of the International Court of Justice, Articles 38(1) (c), (2)

The cloning age has grimly taken off since Dolly the sheep was successfully created through somatic cell nuclear transfer (SCNT) cloning techniques in 1997. This historical landmark and scientific breakthrough occurrence astonished people all over the world. It enforced the world to seriously consider the outcome of the cloning technology if a similar technology would be applied to the humans in the near future. Soon after Dolly, many political leaders and preeminent scholars in a variety of fields almost simultaneously started to discuss and dialogue at national, regional, or international level about moral, ethical, legal, and religious issues substantially involved in the emergence of contemporary human cloning technology.

On 8 March 2005 the United Nations Declaration on Human Cloning (UNDHC) which prohibited all forms of human cloning inasmuch as they were incompatible with human dignity and protection of human life was accepted by the majority member states of the United Nations. Although this Declaration appropriately articulated the consensus attitudes towards the development of human cloning technology, its contents exhibited only a sense of declaration rather than a sense of substantiation. The ambiguity and vagueness of terms used in the Declaration, such as human dignity and human life, unconstructively affected its enforceability and binding effect.

In reality, a universal ban on all forms of human cloning without any exceptions in the international community is not only impracticable but also inappropriate. Human Cloning
technology may not always be a great evil to humans. It may otherwise enrich humans in certain aspects. Along with the evolvement of critical notions of human rights, the merit and prospect of human cloning technology may also be reassessed and resituated today. In order to effectively safeguard the future of humanity through all-around perspectives, the international community may need to assemble again to convene an international convention to construct enhanced international instruments appropriate and suitable to oversee the development of human cloning technology and uphold the part of it which is determined as benevolent and compassionate to the rights and interests of the human being.

**Negative and Positive Rights**: Negative right refers to the right or liberty which a person may prevent the government from deprivation or abridgement without good cause, whereas positive right refers to the right or liberty which a person may request the government to vest and confer. In other words, the government has an obvious obligation to either inaction against a negative right or action for a positive right. Although both rights are categorized as classic rights and have duly recognized since eighteenth century, generally speaking, the former is composed of civil and political rights, whereas the latter is composed of economic, social, and cultural rights.

The objective and function of a human cloning procedure may sometimes link to the realization of a person's right to procreate. The nature of procreative right may generally be

considered as negative right, so that the government may not do any action hindering a person from enjoying having offspring. However, it could also be possibly related to the realization of a positive right if an infertile couple requests the government to actively provide sufficient facilities and choices to aid and help them having a baby. Other than the "traditional" assisted reproductive technique (ART), somatic cell nuclear transfer cloning technique (SCNTCT) may also be a feasible option for an interfile couple. If the government is reluctant to do such action, the petitioner may raise a suit against it under the constitutions of most civilized nations. It may become the responsibility of the court to distinct and clarify the whole aspects of this roaming and zigzagging technology.

Individual and Collective Rights: Generally an individual right protects the individual while a collective right protects a group of people. The latter is also known as group right or solidarity right. The concept of collective right is rooted in the principle of equality and first declared in French Revolution. In accordance with Article 1 and the former part of Article 2 of the Universal Declaration of Human Rights (UDHR) which state: "All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other

status..." the government or society should have an obligation to ensure the dignity and respect of any human being.<sup>244</sup>

It is important to take into account both collective and individual rights especially when a member State is condemned against the equal right of national minority, women, children, indigenousness, aboriginals, and persons with physical disability, rare disease, deform defect, and other chronicle illness as well. It is supposed here that certain genetic defects lead most women of an ethnical group tolerating frequent miscarriage impediments and consequently the ethnical group encounters seriously vanishing dilemma. Members of the ethical group ask the government to provide them with certain state-of-the-art bio-medical techniques and efficient treatment facilities to cure their common diseases and sustain their own ethnical group. Their petitions are initiated not only on individual rights, such as a right to health, care, treatment, or heal, but also on collective rights, such as a right to life, self-determination, development, or culture recognition. If a human therapeutic cloning technique for biomedical research has been proved safe to the human and the risk of resulting catastrophe is as trivial as acceptable, the government may, therefore, has a duly responsibility through every possible mechanism to promptly reply and satisfy their requests.

<sup>&</sup>lt;sup>244</sup> See Universal Declaration of Human Rights, Articles 1, 2

Natural and Sustainable Justices: Natural justice refers to the common standard of fairness to be equally applied to every person in a dispute, while sustainable justice refers to the minimum standard of carefulness to be sympathetically applied to every subject on the earth. The concepts of both justices substantially incorporate the conscience sense of what is right and wrong that is self-evident and does not required a statutory basis. Today, the long-standing concept of natural justice governs all decisions by judges or government officials when they take quasi-judicial decisions.<sup>245</sup> On the other hand, the newly-developed concept of sustainable justice requires nations and peoples to draw up a global action plan for a sustainable development which improves the quality of present human life without compromising the ability Since this concept concerns the equal and fair allocation and of future generations.<sup>246</sup> distribution of justice not only for present peoples, but also for later generations, it is also known as intergenerational justice and sometimes considered by some scholars as one of the third generation of human rights.

Other than where a fertile couple has unequal opportunity to access to the human cloning facility the concept of natural justice may be applicable, with respect to the right to choice and the right to development of the future generations, the concept of sustainable justice may also be

<sup>&</sup>lt;sup>245</sup> See 'Natural Justice," FIFTH DISTRICT COURT LEGAL DICTIONARY, at http://www.fifthdistrictcourt.com/ dictionary/dict-no.htm

<sup>&</sup>lt;sup>246</sup> See WORLD COMMISSION ON ENVIRONMENT AND DEVELOPMENT, OUR COMMON FUTURE (Oxford University Press, 1987); also see Rio Declaration on Environment and Development, 12 August 1992, A/CONF.151/26 (Vol. I)

taken into account if the submission of reproductive human cloning techniques would gravely diminish biodiversity state among future humans. Basically biodiversity in life science concerns the totality of life forms on the earth and focus its enthusiasm to diversity on the level of species, genes, and ecosystems.<sup>247</sup> It is evident that higher level of diversity will ensure a species of life sustainable and protect them from immanent extinction. The loss of diversity on human species may effectively cause the deprivation of free choice and development of the future persons. Therefore, even though there is no international instruments which straightforwardly regard the sustainability of diversity on human genomes after the application of a human cloning technology, such as somatic cell nuclear transfer (SCNT), while encouraging global cooperation on life science for promoting the well-being of humans, the States and people(s) should still have solemnly obligation to pay critical attentions to the prospective and consequence of biodiversity situation on the human being.

Legalism and Moralism: The thought of legalism emphasizes that a rule or discipline can be enforced and obeyed only if it is written by the law. There is no legal duty to act in accordance with any tenet that is not integrated in the law. On the other hand, the thought of moralism insists that any rule or discipline which could be considered as moral law should be

<sup>&</sup>lt;sup>247</sup> See BEN MEPHAM, AN INTRODUCTION FOR THE BIOSCIENCES 284-290 (Oxford University Press, 2005)

followed and complied, no matter whether it is written by the law or not. There is a moral duty to act in accordance with it.

In comparison with the law and morality, the sources of law are majorly resulted from the consensus decisions for the common good recognized by a specific community, whereas the sources of morality are derived frequently from a variety of view and philosophy existing in tradition, custom, ethics, religion, and so forth. In addition, the regime of law is included and confined in the realm of morality. The law is always considered by the scholars as the minimum standard of morality and the lowest measure to maintain the necessary order in a community. However, a violation of law may incurred a punishment with the deprivation of life, liberty, or property of the actor, while a violation of morality may only invite a censure or condemn from the deeper layers of conscience of the actor. The punishment would resort to God the Creator, other super beings, or everlasting cosmos rules in universe, and be retain until the advent of divine judgments or the cycle of next reincarnation.

Basically the compulsory effect of morality is not based on the fear of penalty, but on the realization and believing of the right and wrong described by some ethical and religious tenets. Accordingly, to enhance and maintain a humane society for a long run, the morality can eventually undertake an indispensible responsibility to modify and supplement the shallowness and ineffectiveness of the law. Inevitably and not surprisingly a Legalism-Moralism approach

which regards the law and morality, respectively, as either side of a coin is recently emerging in the international community.<sup>248</sup> Based on a Legalistic Moralism analysis, an international instrument which concerns the development of current human cloning technology should not limit its effort to legal regime only. Many subject matters involving in the science of human cloning, such as human life or dignity, familial or societal value, respect for being or life, etc, cannot be properly defined or situated by the law.

To optimize the well-being and prosperity of both present and future humans, it is necessary for the international community to construct an effective mechanism to oversee the cloning science and its consequence to the human being. The mechanism created by the international instrument should go beyond the confinement of legalism. Furthermore, it may observe commonly-acceptable moral imperatives derived from civilized religions, ethics, traditions, or other similar sources, as general principles of international law and solemnly apply the morality as a binding norm into international disputes related to the field of human cloning technology.

For example, an international instrument may acknowledge the moral right to life of the unborn embryos and the dignity of the mothers as well, and guarantee such interests and impose

<sup>&</sup>lt;sup>248</sup> See Judith Goldstein, Miles Kahler, Robert O. Keohane, & Anne-Marie Slaughter, *Legalization and World Politics: An Introduction*, in LEGALIZATION AND WORLD POLITICS 1-8 (Judith Goldstein, Miles Kahler, Robert O. Keohane, & Anne-Marie Slaughter, eds., The MIT Press, 2001)

related responsibilities on the actors and the States in its by-law provisions.<sup>249</sup> To ensure the enforceability of this international instrument, certain reprimand, denounce, censure, condemn, boycott, suspension, or other forms of punishment may be initiated when a violation of its provisions is intentionally committed by an actor or a State.

## **III.** International Consensus to Sustain the Exploration of Cloning Science

Good science may also be an ethical science. Although human cloning for therapeutic purposes may offer a variety of opportunities to promote and maintain health and welfare of the human being, as pointed out by the U.S. Department of Justice, it would be virtually impossible to enforce a ban only on human reproductive cloning. If cloned human embryos can be produced in labs for research purposes, there would be no way to ensure the prohibition of human cloning for reproductive purposes as they might be implanted in surrogate women and brought to birth. Furthermore, research cloning requires the harvesting of millions of eggs from women. The egg harvesting process not only endangers women by placing them at a higher risk for ovarian cancer, infertility, and other health hazards, but also exploits women by treating them

<sup>&</sup>lt;sup>249</sup> See Shaun D. Pattinson, *Timothy Caulfield, Variations and Voids: the Regulation of Human Cloning around the World,* 5 BMC MED. ETHICS 9 (2004)

as mere egg-making machines. These results would not be acceptable by any traditional civilizations and humane societies.

Likewise, a systematic ban on human cloning may be quiet illogical. Some scientists contend that the embryos used in research cannot technically be considered babies with limbs or brains. Even if the embryos possess great potential to become a human person, they are at this stage only a mass of stem cells. Using them for research can significantly enhance the scientific exploration of human knowledge for the public good. However, it is an unquestionable scientific conclusion that human life begins at the single cell embryo stage. Research cloning will as anticipated exterminate embryonic human beings and destroy human life. Furthermore, numerous studies do insist that current therapeutic benefits of medical treatments may be ethically derived from adult stem cells and umbilical cord blood and cells. If stem cells from sources other than embryos are found to have the same potential as embryonic stem (ES) cells, the use of those stem cells will be preferred and the exploitation of embryonic stem cells ought to be reevaluated.

A humane society should not always remain silent or indifferent on yea or nay on matters of human cloning technology. While considering the benefits and advantages of human reproductive and therapeutic cloning, some motto imperative ideals on the mainstream of the international community, such as human dignity, respect for life, familial value, and so on, should also be prudentially regarded as well. The international community shall have the right and responsibility to consensually draw a clear line in scientific research on human cloning. Those explorations of cloning science which are in conformity with imperative legal and moral norms commonly recognized in current society and essential to humanity and humane civilization, such as respect for autonomy, sympathy with life, beneficence on the weakness, and non-maleficence to the vulnerableness, and other similar higher level principles, may justify the coordinate support and sustain ratified by the international community.

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