THE LOGICAL NEXT STEP? AN INTERNATIONAL PERSPECTIVE ON THE ISSUES OF HUMAN CLONING AND GENETIC TECHNOLOGY

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"If you're a scientist, you believe that it is good to find out how the world works; that it is good to find what the realities are; that it is good to turn over to mankind at large the greatest possible power to control the world . . . ."

- Robert Oppenheimer on the Manhattan Project

"Thou shalt have no other gods before me . . . ."

- Exodus 20:3

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I. INTRODUCTION

Imagine a child, about eight years old, playing touch football in the front yard with a group of neighborhood kids; a model youth, cute, kind, and relatively bright for his age. A pass is overthrown and bounces into the street; a street, like any other, located in the middle of a quiet neighborhood, in any city, anywhere. As the child chases the ball, he runs into the path of an unexpected car driving down the road. Killed on impact, the parents of the child, their only child, are devastated. They are unable to have anymore children, and feel they have lost their one and only chance to have a child. After a few months, the grief stricken parents are approached by a local fertility clinic and are given a proposal that could afford the couple an opportunity to not only have another child, but to have their child recreated. The procedure they described would use stem cells from the blood taken from the woman's umbilical cord, which was extracted and preserved at the time of her child's birth. The cells would then be placed inside an enucleated egg cell and implanted in the woman's uterus, where it would be allowed to develop naturally. Although wary of the process, but still stricken over the loss of their only child, the couple is assured of the safety of the procedure and elects to proceed. Nine months later, a beautiful baby boy and identical genetic copy of the deceased child, is born.

Now imagine this same situation, but instead of promising an identical genetic copy of the deceased child, the clinic offers to manipulate the genes and perhaps produce a girl, or another boy, but one with blue eyes and blond hair. Even more convenient, the clinic has a special menu allowing the couple to choose which traits the child will have, with choices available for intelligence, hair color, physical build, etc. Instead of being hit by a car, say the child dies due to a serious genetic disease. The opportunity may be available to produce an exact clone of the child, less those genes that are susceptible to the disease, or if need be change the sex of the child so that the disease will not become viable. Is this the future of child birth which we can expect with regard to the new technologies now under public and legislative debate?

Man is on the threshold of a new world, in which the ability to alter the very essence of humanity and its interaction with nature, is upon us. Through the science of genetic engineering the manipulation of the genetic composition of man, and that of all future generations, has advanced to the point where serious rational thinking must direct the potential course of progress in the areas of cloning and genetic technology. The goal of science is to produce the truth, and not peace of mind. Due to the conflict with moral, ethical, legal, and social issues, the pursuit of

scientific research must be limited within the bounds declared by all of mankind. These technologies, if applied to humans, will significantly alter the direction of the whole of humanity, in its efforts to improve upon the overall health and condition of society. For those who are concerned with the future debate over human rights, awareness of the potential scientific and technological advances must be achieved. If not, a lack of understanding on which questions should be asked, and what answers must be given will ensue. The sooner these issues are brought to the attention of every individual, the more beneficial the technology will become to all of humanity.

II. ADVANCEMENTS IN CLONING TECHNOLOGY

Experimentation with animals utilizing cloning technology has been going on since the 1950's when scientists began to attempt the cloning of frogs. These early scientists used a procedure in which they took the nuclei, which harbors the DNA, of cells from tadpoles and in turn implanted them into nuclei-free fertilized frog eggs.[1] Attempts using this process resulted in many of the frogs dying soon after emerging from the eggs, and those that survived were grotesquely deformed or sterile.[2] Within twenty years, scientists reached the level of successfully cloning frogs, although prior to reaching adulthood the frogs were killed.[3] As the success in the cloning of frogs was achieved, scientists began to experiment with the cloning of other animals. During the 1980's, the first cattle, lambs, and piglets were cloned from the splitting of embryos.[4] However problems still exist. For example, cattle embryos grow twice as large as normal in the womb; sometimes killing both the calf and the mother.[5]

A major breakthrough was accomplished in the 1980's by Robert McKinnell at the University of Minnesota. Mckinnell was able to clone frogs from 2- to 4-celled embryos using nuclear transfer.[6] Scientists extracted the nucleus from an embryonic cell of one species of frog and fused it with an egg from another species of frog whose nucleus was

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1. Charles Seabrook, *ScienceWatch A Mirror Science*, ATLANTA J. & ATLANTA CONST., Mar. 9, 1997, at C4.

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

6. Clair Wood, *Here a Sheep, There a Sheep .. And Human*, BANGOR DAILY NEWS (Me.), Feb. 28, 1997.

previously removed.[7] The resulting frog was an exact clone of the species providing the nuclear material. By 1984, nuclear transplantation had been used to successfully clone mice.[8]

In 1993, the advancements accomplished in cloning techniques reached world wide attention with the announcement by researchers at George Washington University. Utilizing an embryo splitting procedure, scientists created four individual human embryos by splitting a single human embryo at the 4-cell stage. Once the original embryo was split, each individual embryo was covered with an artificial zona pellucida, the protein covering an egg, and allowed to continue to divide, with some reaching the 32-cell stage.[9] Upon reaching the 32-cell stage, the embryos would have been able to be implanted into a woman's uterus.[10] In order to ensure that these embryos would not be able to develop into human beings, scientists selected embryos that were fertilized twice. Thus, these embryos co ntained an extra set of chromosomes which ensured that they would die sometime during their development.[11] Theoretically, this technique could potentially be used to create an infinite amount of clones, all derived from one original cell, and developed into genetically identical human beings. Although these embryos were never implanted, and were destroyed after six days, the breakthrough caused a public uproar over the ethical implications of the procedure.[12]

According to scientists involved with this research, one of the purposes for proceeding with this procedure was to elicit public debate over whether this type of cloning is acceptable.[13] Although the scientists were successful in gaining the attention that this research attained, the responses may not have been exactly what they were looking forward to. Negative reactions were received from fellow scientists, ethicists, and the general public. Because of this public reaction and until some type of concrete guidelines are developed, the scientists stated that they would suspend further research into the cloning of human embryos.[14] In defense of the research, project leader Dr. Hall responded, "We have not created

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7. *Id.*

8. *Id.*

9. Philip Elmer-Dewitt, *Cloning: Where do we Draw the Line*, TIME, Nov. 8, 1993, at 64.

10. *Id.*

11. *Id.*

12. Mona S. Amer, *Breaking the Mold: Human Embryo Cloning and its Implications for a Right to Individuality*, 43 UCLA L. REV. 1659, 1665 (1996).

13. *Id.*

14. *Id.*

human life or destroyed human life in this experiment."[15] Furthermore, scientists involved in this type of cloning research believe that as the logical progression that began with in vitro fertilization, human cloning is the next step in relieving human suffering from infertility, as well as many other therapeutical needs.[16]

International reaction to the research conducted at George Washington University was also mainly negative. The majority of countries, as well as international organizations, condemned the experiments and set forth an international debate on whether these types of experiments should be conducted on human beings. Prior to this, only a handful of countries had regulations that would prohibit these types of experiments on humans, but even these regulations were not specific enough to prohibit all types of experimentation. Germany stood out and had this research been conducted there, the scientists would have the potential to face up to five years in prison.[17] Other countries, such as England, had regulations that were thought to protect against human cloning by requiring a governing body to issue a license prior to any research being conducted.[18] But, as will be shown, the regulations were not prepared to cover all types of cloning techniques.

In 1997, at the Roslin Institute in Scotland, researchers, led by Dr. Ian Wilmut, performed what was thought of as an impossible task, and thus brought the world into a new dimension in cloning technology. Scientists there, were able for the first time to clone an adult mammal utilizing somatic cell nuclear transfer. Beliefs, prior to this experiment, were that DNA would not be able to guide the development of an embryo more than one time.[19] Thus, it was thought that cloning an adult mammal would be an impossible process. But with the birth of Dolly the sheep, scientists and the world are now confronted with a new technology that will most likely alter the future of human life.

What the scientists created was a sheep that contained the genetic material of only one parent and is basically a delayed twin of the adult sheep that donated the genetic material. To accomplish this task, scientists fused a normal adult cell and an unfertilized egg with no nucleus and allowed the new genome to began its dividing process. A viable embryo was created after 277 attempts, and was reimplanted into another ewe. In

15. Elmer-Dewitt, *supra* note 9, at 64.

16. *Id.*

17. *Id.*

18. *Id.*

19. Clive Cookson, *FT Guide to: Cloning*, FIN. TIMES, Mar. 3, 1997, at 10.

all, eight lambs were created, including Dolly, out of 834 fused pairs, one of which died immediately after birth.[20]

The success accomplished by the scientists at the Roslin Institute has the possibility to lead to great gains in the breeding of animals. With the ability to clone an adult mammal, scientists can replicate an animal with already known desirable traits. The breeding of sheep with fine wool, horses with great speed and power, cows with desirable milk qualities and nutrients, are some of the endless possibilities. Speculation within the scientific community is that within ten years, the breeding of animals with the capability to produce organs that are fit for human transplantation without the possibility of rejection is possible.[21]

Applying this technique to other mammals, including human beings, does not seem feasible at this time because many problem areas arise. First, there are many differences that exist between mammalian species in how they develop during the first few days of growth. The DNA of mammals differ in how quickly they take charge in the embryo's development process.[22] The embryos of different species will also differ in how they implant in the uterus and develop the placental connection.[23] A second problem area exists with current knowledge about the reprogramming abilities of the fused DNA.[24] At the present time, scientific knowledge of how normal programming occurs during development is lacking; thus, one can imagine the uncertainty in the reprogramming of DNA when it is stripped of its old proteins and replaced with the new ones inside the egg cell.[25] Other problem areas include the current success rate of attaining a viable embryo from the fused egg cells,[26] and the risk of mutated DNA being transferred from the adult into the new embryo.[27]

III. TECHNIQUES USED IN CLONING

There are two main techniques utilized when researching cloning technology. The first is called blastomere separation and consists of

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20. *Prohibition of Fed. Funding for Human Cloning Research, 1997: Hearings on H.R. 922 Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. (1997).

21. Mona Charen, *Is Cloning a Victory over Death*, DET. NEWS, Feb. 27, 1997, at A15.

22. Elizabeth Pennisi & Nigel Williams, *Will Dolly Send in the Clones*, SCIENCE, Mar. 7, 1997, at 1415.

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.* The success achieved in Scotland occurred in only 1 out of 277 attempts.

27. *See* Mark Ward, *The Sheep that Shook the World 'Dolly' Offers Much More Hope than Hazard*, MILWAUKEE J. & SENTINEL, Mar. 2, 1997, at 1.

splitting an original embryo; thus, creating multiple embryos, each containing the identical genetic composition. This technique has been used since the fifties to clone plants and animals and was the process behind the experimentation conducted at George Washington University on human embryos. The second technique, and the one which created the recent public debate over cloning technology, is somatic cell nuclear transfer. This cloning process basically entails replacing the nucleus of an unfertilized egg cell with the nucleus from another person's cell, containing their DNA; thus, allowing the replication of desirable traits in the resulting offspring. It is this technique, which was successfully performed in Scotland on the sheep, which has called for the countries of the world to enact regulations restricting the area of genetic research.

Embryo splitting, also called blastomere separation,[28] is the older and somewhat simpler of the techniques used in cloning. This technique creates multiple embryos with identical DNA by splitting the original embryo; thus, creating the possibility of implanting these newly created embryos into a woman's uterus and allowing them to develop into identical human beings.[29] In a theoretical sense, embryo splitting can be utilized to produce an infinite amount of identical humans, each one derived from an embryo which is either natural or one that is artificially created. Currently, this type of cloning is done from embryonic cells, which are removed from an animal's embryo at an early stage when it is still developing.[30] Because of this, predetermining the genetic traits for those that are desirable is not available.

Blastomere separation is the technique that was used by scientists at George Washington University to clone human embryos, and is readily available at many laboratories and fertility clinics around the world.[31] The technique involves acquiring an embryo and allowing it to develop in a petri dish until the 2- to 8- cell stage.[32] A chemical solution is then added to the dish that dissolves the zona pellucida covering the embryo.[33] Once the zona pellucida is dissolved, the cells contained within the embryo are

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28. Amer, *supra* note 12, at 1660.

29. Elizabeth Ann Pitrolo, *The Birds, the Bees, and the Deep Freeze: Is There International Consensus in the Debate over Assisted Reproductive Technologies*, 19 HOUS. J. INT'L L. 147, 157 (1996).

30. *Human Cloning Techniques* (last updated Feb. 29, 1996) <http://cac.psu.edu/~gsg109/qs/em01002.html>.

31. *Id.*

32. *Id.*

33. *Id.* The zona pellucida is a protective protein and polysaccharide membrane that covers the internal contents of the embryo, and provides the necessary nutrients for the first several cell divisions that occur within the embryo.

freed.[34] These embryonic cells, also known as blastomeres, are then collected and placed in separate petri dishes.[35] An artificially produced zona pellucida is then used to coat the embryonic cells and each cell is now considered to be a new embryo. Each embryo will contain identical genetic information and if allowed to develop, they will divide and eventually form a human being.[36]

There are many benefits that arise from this type of splitting procedure, as well as many detrimental effects that may ensue. The moral, legal, and ethical issues will be discussed in more detail later in this article, but some of the more prevalent benefits and problem areas deserve mention here. For example, through the research conducted at George Washington University, scientists were able to gain some knowledge on how to achieve the best results in dividing embryonic cells.[37] Studies showed that embryos that were split during the 2-cell stage achieved greater success in reaching the 32-cell stage, which is the stage at which implantation in a uterus is available.[38] Those embryos that were split at the 4- to 8-cell stage were fortunate to reach only a 16-cell stage.[39] As mentioned earlier, the embryos experimented on at George Washington were destined to die at an early stage and were denied the possibility of producing a human being because they were fertilized twice by more than one sperm cell.[40]

Another area of debate is that if this procedure is performed successfully on viable human embryos, cloned embryos could be stored frozen and then later thawed out for use in fertility procedures. The thawed embryo could be used by some parents to create a later born genetic twin or used to develop a replacement for a child who prematurely died. Embryo splitting may also increase the amount of embryos that are available for use during fertility procedures by limiting the need for putting the woman at extended risk during additional egg retrieval surgeries. Blastomere separation can at least double the amount of embryos that are retrieved during one embryo retrieval surgery.[41] Apart from the potential benefits that may arise, there are many issues that must be resolved

34. *Id.*

35. *Id.*

36. *Human Cloning Techniques*, *supra* note 30.

37. *Id.*

38. *Id.*

39. *Id.*

40. Elmer-Dewitt, *supra* note 9.

41. June Coleman, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1357 (1996).

concerning the ethical and legal effects of this procedure. First, this type of research is still highly experimental and potentially risky for the embryo.[42] Also moral issues surrounding the creation of life and psychological effects on the cloned child and donor child, as well as those for the parents and society at large must be considered.

The second and more difficult procedure is nuclear transfer, also called somatic cell nuclear transfer. According to scientists, the cloning of an adult mammal utilizing this technique was thought to be impossible until early in 1997. At this time a research team at the Roslin Institute in Scotland performed successful nuclear transfer to clone an adult sheep. Making the experiment even more dynamic is that three breeds of sheep were used in the process. The cell nucleus from a Finn Dorset sheep was substituted for the nucleus of an egg from a Poll Dorset, which was then implanted in a Scottish Blackface ewe.[43] The success of this research brought the debate over cloning technology, and the scientific and medical possibilities that may now be available, to front page news and elicited a furor of public and governmental debate over this new technology. Ethical, legal, and moral issues concerning the implications of utilizing the new biotechnical advances on the human race were, and continue to be, debated in legislatures, laboratories, and public places throughout the world. Somatic cell nuclear transfer of adult mammals now opens the door to the possibility of producing human beings with predetermined desirable traits.

Nuclear transfer, unlike embryo splitting, is a difficult procedure with a much lower rate of success.[44] As of the beginning of 1997, there were only six research facilities around the world with the capability of performing the same procedure as researchers at Roslin.[45] The procedure was accomplished by transferring the nucleus from an udder cell into an egg, whose DNA had been previously removed.[46] In order to be successful, scientists had to make the donor cell DNA behave much like the DNA of a sperm or unfertilized egg. This was achieved by depriving the cells of the full amount of nutrient-laden serum that is naturally supplied and in effect caused the cells to remain in the beginning stages of the cell cycle.[47] Causing many of the genes to shut down, this deprivation

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42. *Id.*

43. Christopher Wills, *A Sheep in Sheep's Clothing*, DISCOVER, Jan. 1998, at 22.

44. *See* Ward, *supra* note 27.

45. *Id.*

46. Pennisi, *supra* note 22.

47. *Id.*

ensured that the DNA had not replicated just prior to being transferred.[48] Using an electrical charge, the researchers then fused the donor cell with an unfertilized chromosome-extracted egg.[49] This new fused egg was now provided with a full complement of DNA from the original donor sheep and the egg began to divide and develop.[50]

In applying this technique to humans, as well as other mammals, a potential problem arises in how fast, in individual species, the DNA takes control of the development process. In this procedure with sheep, the first three cell divisions, the 8-cell stage, of the egg replicates its DNA without expressing any of the new genes, and all the work necessary for cell division comes from proteins and messenger RNAs contained in the original egg's unextracted cytoplasm.[51] During this process, the DNA loses its attached proteins and picks up the proteins contained in the cytoplasm, which in turn reprograms the DNA so the normal development of the embryo can occur.[52] While in sheep the DNA apparently gained control in the 8-cell stage, in humans, on the other hand, the new DNA is thought to take charge only after the 4-cell stage.[53] Overcoming this difference is detrimental to having success in this technique for human beings. Scientists also believe that the mammary gland cells used to attain the transferred DNA for the sheep included stem cells. Stem cells have a greater potential for development because they are an indifferentiated progenitor cell as compared to an ordinary epithelial cell.[54]

While negative reaction to the success achieved in this research has caused many countries to pass laws outlawing the use of this technique to clone human embryos, most of the current regulations use language that is too broad to condemn all experimentation. For example, under Britain's Human Fertilization and Embryology Act of 1990, human cloning is prohibited.[55] But the language used relates to the replicating a nucleus of an embryo with a nucleus taken from the cell of a person.[56] Furthermore, in defining an embryo, the Act states that an embryo means a live human embryo where fertilization is complete, or an egg in the process of

48. *Id.*
49. *Id.*
50. Cookson, *supra* note 19, at 10.
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. Human Fertilization and Embryology Act, 1990, § 3(3)(d), (UK).
56. *Id.*

fertilization.[57] Therefore, based on the language of this Act, the research conducted at the Roslin Institute may not have been included in the prohibition, if proceeded on with humans, because no embryo was involved in the creation of the sheep.[58] Also, the cell that developed was not a gamete, a combination of sperm and egg, nor did it undergo fertilization.[59] In order to ensure protection from this type of cloning, regulations must become more specific in what exactly it is trying to prohibit.[60] Language used should also not be too over-reaching and overbroad; thus, preventing other types of research from being conducted that does not necessarily involve cloning.

IV. GENETIC ENGINEERING TECHNOLOGY

As a way to more completely understand a majority of the issues that are raised in proposing legislation regarding the restriction of cloning technology, a short introduction into other methods of genetic manipulation is discussed under this topic. Some of the procedures are currently utilized in genetic research by scientists, while others have the potential to be used in the near future. The relation of these technologies with that of cloning will become apparent as people understand the capabilities of science, even at this infant stage of knowledge. The dangers associated with utilizing the advancements in genetic manipulation by altering the constitution of the human genome, with that of cloning, creates fears of a mass produced predetermined society. This topic will provide only a limited discussion in these areas; highlighting the areas in which they relate to subject of cloning.

A. IN VITRO FERTILIZATION

In vitro fertilization is the process of uniting an egg and sperm outside the woman's body. During the procedure, usually seven or more eggs are surgically removed from a woman's ovary and, after maturing for approximately six hours, are combined with sperm and allowed to incubate for another twelve hours.[61] The removal of excess eggs is done to protect the woman against the future risks of repeat surgical procedures and

57. *Id.* at § 1(a), (b).

58. Sharon Korek, *Following Dolly*, 47 NEW L.J. 428, 429 (1997).

59. *Id.*

60. *Id.* at 430. Such a rewording might read, "embryo means a live human embryo where fertilization is complete or where a cell has been modified, created, or altered such that it has the potential to develop into an embryo or fetus."

61. Coleman, *supra* note 41, at 1337.

hormonal therapy.[62] Two to four of the fertilized eggs are then implanted into the woman, who has undergone hormone therapy to prepare her uterus for the procedure.[63] All steps included, the complete procedure will take approximately two weeks with a basic cost of around $8,000.[64] The unused fertilized eggs are then frozen[65] for use in the event a live birth does not result from the first implantation, or future pregnancies are desired. The eggs could also be used for research or for donation to another woman.

Internationally, in vitro fertilization, when used as a remedy for infertility, seems to have become a sanctioned technique and is regarded as a routine commercial transaction.[66] There are still differing views on the legal and moral status of pre-implantation embryos and embryo research between the nations of the world and until a consensus opinion is derived worldwide many problems will continue to persist. Currently, most research and experimentation on human embryos is financed with private funding, including funds from the IVF industry; thus, any government legislation should be focused on the procedures themselves and not on the funding the research receives.[67] With only about a ten to twenty percent chance of achieving a pregnancy with one embryo, proponents of in vitro fertilization and cloning technology argue that the odds for a successful pregnancy would increase significantly, if that one embryo can be cloned into three or four. [68]

B. GENE THERAPY

Gene therapy consists of attempting to alter the genetic makeup of an individual by either deleting or inserting specific genes in order to enhance one's genetic profile.[69] Alteration takes place by adding or removing DNA to, or from, a defective gene in order to overcome the consequences of disease.[70] Through the efforts of projects, such as the Human Genome Project, scientists will be able to identify and locate the

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62. *Id.*

63. *Id.* at 1338.

64. Pitrolo, *supra* note 29, at 152.

65. *See* Coleman, *supra* note 41, at 1338. Remaining embryos are frozen in liquid nitrogen at -196 degrees centigrade in a process called cyropreservation; Pitrolo, *supra* note 29, at 152. Storage life of preserved human embryos may be from five to ten years.

66. Pitrolo, *supra* note 29, at 152.

67. Elmer-Dewitt, *supra* note 9.

68. *Id.*

69. Ralph C. Conte, *Toward a Theological Construct for the New Biology: An Analysis of Rahner, Fletcher, and Ramsey*, 11 J. CONTEMP. HEALTH L. & POL'Y 429, 435 (1995).

70. *Id.*

genes that are responsible for the development of humans. While many will infer a eugenic philosophy is behind such a procedure, proponents of this technology state that the overall quality of human life is improved because individual and societal suffering will be reduced and in turn the individual and subsequent offspring are genetically more viable.[71] Currently, there have no been no reports of using gene therapy on human subjects, but the use of these types of procedures is becoming increasingly possible and probable.[72] Gene therapy does have the potential to help cure many diseases such as sickle-cell anemia, hemophilia, and cancer.[73]

Depending on the type of cells being altered, gene therapy can take two forms. Somatic cell alteration is the first type of gene therapy. In this process, alterations are made to those cells which make up a person's tissues or organs, known as somatic cells, and results in changes to only that individual and not their subsequent offspring.[74] Of the techniques used in gene therapy, somatic cell alteration poses less of an ethical problem because the process is complete with the individual, rather than altering future generations of humans, and provides a beneficial and therapeutic result.[75] The second and more controversial of the techniques is gametic genetic therapy. This type of gene therapy seeks to alter the genetic profile of both the individual and subsequent offspring by modifying the gametes, the sperm and egg used in fertilization.[76] By replacing a defective gene from an individual's genetic profile, the goals are to help either cure or alleviate the effects of a disease and also prevent the passing of the gene to future offspring. Besides the highly debated issue of interfering with human evolution, gametic genetic therapy also possesses the risk to nonconsenting individuals of contracting previously made errors from the original procedure.

C. *GENETIC SCREENING*

Through technological advances, preimplantation genetic screening is available to prospective parents to evaluate human embryos for genetic defects and disease. For example, screening can be used to determine if a child is the recipient of a defective gene caused by the parents' genetic profile containing an inheritable disease. Because of success in the fields

71. *Id.* at 437.

72. Coleman, *supra* note 41, at 1354.

73. *Id.*

74. Conte, *supra* note 69, at 436.

75. *Id.*

76. *Id.* at 435.

of in vitro fertilization, cyropreservation, and embryo biopsy, human embryos can be screened prior to implantation, for genetic defects and disease.[77]

Similar to a normal in vitro fertilization procedure, the woman's egg cells are removed and fertilized with sperm outside the body.[78] Upon achieving the 8-cell stage, one cell is removed from each embryo, through a vacuuming procedure, and DNA analysis is performed. From the genetic testing, scientists are able to identify the embryos that are free from disease and these embryos are then implanted back into the uterus to continue development.[79] Currently, screening procedures have been successful in locating diseases such as cystic fibrosis, Duchenne muscular dystrophy, Tay-Sachs disease, and thalassemia.[80] With continued research, scientists may be able to detect more diseases and work towards methods of prevention and as an ultimate goal, their extinction.

D. EUGENICS

Eugenics can be described as a process in which technology is utilized to improve the human genetic profile and in turn improve the human species as a whole. This can occur positively, through the development of desirable or superior traits, or negatively, by reducing or eliminating less desirable genes.[81] Although the mere mention of eugenics connotes the memory of the atrocious experiments conducted by the Nazis, eugenic practices currently take place in the United States and throughout the world. Required testing for couples with inheritable diseases, statutes prohibiting incest, and pre-birth knowledge of the child's sex or genetic defects which may result in an abortion, can all be described as negative eugenic practices.[82] The detection and sterilization of many unwanted genetic diseases, such as sickle cell anemia or Tay-Sachs disease, allows the parents the choice of whether or not to reproduce or avoid a pregnancy.

Eugenic ideology has been present in society dating back to Plato's *Republic*, in which he sponsored the ideal that through selective breeding,

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77. KARL DRLICA, UNDERSTANDING DNA AND GENE CLONING 275 (John Wiley & Sons, Inc. 1997).

78. *Id.*

79. *Id.*

80. *Id.*

81. John R. Harding Jr., *Beyond Abortion: Human Genetics and the New Eugenics*, 18 PEPP. L. REV. 471, 477 (1991).

82. *Id.* at 478, 479.

the foundation of a superior class of beings can be formed.[83] In the 1800's, Sir Francis Galton, cousin of Charles Darwin, chose the term eugenics to describe the process of selective breeding in humans, which would allow those superior blood lines to prevail over less suitable breeds.[84] During this time, Gregor Mendel began the ground work for today's genetic research by experimenting with the selective breeding of pea plants.[85]

Scientists in the United States became involved in eugenic philosophy and genetic technology in the early 1900's. The fear that immigrants and lower class people would overpopulate the United States and cause a social decline flourished and prevention of their procreation was advocated. In 1912, the United States Public Health Service began testing incoming foreigners to determine intelligence and the extent of their feeblemindedness.[86] As a result, the Immigration Restriction Act of 1924 was enacted and mandatory quotas were selected limiting the amount of immigrants from a particular country from entering the United States.[87] Eugenically motivated, laws permitting involuntary sterilization of certain groups were enacted in thirty-two states by 1932.[88]

The decline of the eugenic movement began with the decision handed down by the Supreme Court in *Buck v. Bell*, upholding the constitutionality of a Virginia compulsory sterilization statute.[89] Although the statute was upheld, the popularity of the movement began to fade and several states began removing these types of laws from their books. Around this same time, researchers in psychology and sociology began to associate the influence of the environment with genetics in determining one's characteristics.[90] With the publicized eugenic experimentation conducted by the Nazis, the movement was all but dead and research seemed to be headed into a different direction. That was until 1953 and the postulation of the double helix of DNA as the chemical basis of hereditary was discovered by Watson and Crick.[91] This event, included with the success achieved in breaking the DNA code, began what is known

83. *Id.* at 480.

84. *Id.*

85. *Id.*

86. *Id.* at 481. According to the tests - 83% of Hungarians, 87% of Russians, 83% of Jews, and 79% of Italians demonstrated a source of feeblemindedness.

87. Harding, *supra* note 81, at 481.

88. *Id.*

89. *Id.*; *see* Buck v. Bell, 274 U.S. 200 (1927).

90. Harding, *supra* note 81, at 482.

91. *Id.* at 483.

as the New Eugenics and brings us to the advancements that were recently achieved.

E. HUMAN GENOME PROJECT

The Human Genome Project is an international collaboration of countries and scientists working together in an effort to map and sequence the entire human genome. It is intended bring together and organize the work produced by hundreds of laboratories in dozens of countries, in order to decode the secrets of the human genome. Among the many goals of this project are to discover more effective ways to treat and prevent disease, increase genetic screening abilities, and of greatest importance, reduce pain and suffering throughout the human species. Theoretically, once a map of human genome is complete, scientists and physicians will be able to screen an embryo for both beneficial and deleterious genetic characteristics.[92] Medically, potential genetic disorders could thus be predicted and prevented and normal genes identified in order to augment current scientific knowledge.[93] Because of a rekindled belief that genes, rather or at least to a greater extent than environment, determine an individual's intelligence, longevity, health, and other personal characteristics, the project looks to a future of parental selection and control over offspring characteristics and greater screening capabilities, which will in turn lead to an increase in the abortions of fetuses containing genetic disease.[94]

Internationally, countries are working together to organize their respective works in order to rapidly gain success in the mapping and sequencing of the human genome. The United States, which began the Project, is the largest contributor and has allocated at least three billion dollars to the fifteen year initiative, making it the most expensive biology study ever conducted by the United States.[95] The United States had initially focused their research in the mapping of the genome rather than the sequencing,[96] but because of positive assessments, new goals for the project

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92. Conte, *supra* note 69, at 434.

93. *Id.*

94. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 422 (1996).

95. *Human Genome Project* (visited Sept. 26, 1997) <http://cac.psu.edu/~gsg109/qs/em02002. html>.

96. G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AIPLA Q.J. 27, 29 (1994). The decision to initially focus efforts on mapping the human genome rather than total sequencing was based on the enormous size of the human genome, which comprises approximately three billion basepairs, with the specific order of the basepairs encoding genetic information. The necessary technologies were already available to map genes onto chromosomes, thus increasing map resolution was given priority, with

have been drafted.[97] In Great Britain, the thrust of the research has been in creating cDNA libraries and the mapping and sequencing of cDNA clones.[98] France has been a major contributor to the research by working on the construction of a human genetic map based on known DNA markers. Italy has also pitched in spreading around their research into the fields of preparing cell lines and mapping, gene sequencing, and working on improving the speed of current gene sequencing.[99]

Varying opinions on the legitimacy and moral implications concerning this type of project have kept some countries from participating, but others are beginning to contribute. Japan, who previously thought the project was not "pure science," has recently been active in developing and improving instrumentation and techniques for automated DNA sequencing.[100] While a total genome project has been discouraged because of its possible eugenic implications, Germany has even begun to participate, focusing their study on genetically inheritable diseases.[101] The United Nations became involved in the international effort in 1988, with the creation of the Human Genome Organization. The organization, referred to as HUGO, was established to coordinate the researchers from different countries in order to avoid duplication of efforts and unnecessary competition. HUGO was also created to foster public debate on the issues of scientific, ethical, legal, and commercial implications of the various genome projects.[102]

The Human Genome Project has not escaped heavy criticism and legal and moral challenges have been presented against the funding of such a study. Although the Project has been successful in locating the genes for some diseases,[103] opposition is strong and persistent. The lack of respect towards individual autonomy and uniqueness are the most frequently presented arguments, but other concerns do arise. Criticism over the enormous funding this project has garnished is another issue that is much debated. Because only approximately two to five percent of the human genome is supposedly of potential use to scientists, critics argue that

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sequencing of known genes to follow. Total genomic sequencing would complete the latter stages of the project.

97. *Id.* at 29.

98. *Id.* at 34.

99. *Id.* at 32.

100. *Id.* at 34.

101. *Id.*

102. Kettelberger, *supra* note 96, at 37.

103. *Id.* at 42. As a direct result of the Human Genome Project, the locus for myotonic dystrophy, a form of muscular dystrophy that affects 1 in 8500 people, was recently discovered.

funding should be allocated to lesser fields of study that are fundamental to the research of these larger more expensive projects.[104]

V. INTERNATIONAL AND DOMESTIC LEGISLATION

In evaluating the existing and proposed legislation from around the world, it must first be understood that any success achieved in the areas of cloning human beings and other biotechnologies will have an enormous impact on all of humanity, including all future generations. The potential ability to produce and control the development of human beings, enhancing the favorable genetic characteristics, while eliminating unwanted traits, will enable man to not only exhibit God-like powers, but to determine the fate of humankind, as we know it today. These are issues which concern every person, in every walk of life, throughout the world, and which all countries must work together, as one, to ensure that mankind as a whole is capable of handling this awesome power. In today's world, described as a global-community, ease of communication and transportation must force countries to work in unison to ensure that the best result for the benefit of all of humanity must prevail. Anything less would create an atmosphere of procreative tourism, in which people will travel to those countries offering less restricting reproductive choices.[105]

Currently, legislation is based on the ideological beliefs expressed within a particular country. For example, legislation in Great Britain is based on the principle of individual freedom.[106] Thus, human embryo research and the availability of artificial reproductive technology is permitted, and in some cases encouraged.[107] German legislation, on the other hand, is inspired by the principle of human dignity, and as such research on human embryos is severely restricted or completely prohibited.[108] Religious beliefs also play a major role in this area of legislation, contributing to the moral and ethical implications that must be protected against. In France, Christianity has been influential in legislation protecting the principle of human dignity.[109]

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104. *Id.* at 38. Only 50,000 to 100,000 genes are estimated to be contained within the human genome. The remaining 95-98% of the genome is defined by some as junk and of little or no use.

105. Bartha M. Knoppers & Sonia LeBris, *Recent Advances in Medically Assisted Conception: Legal, Ethical, and Social Issues*, 17 AM. J. L. & MED. 329, 333 (1991).

106. Noelle Lenoir, *French, European, and International Legislation on Bioethics*, 27 SUFFOLK U. L. REV. 1249, 1252 (1993).

107. *Id.*

108. *Id.*

109. *Id.* at 1259.

Similarities do exist among the laws of many countries, although it must be reiterated that with these technologies it is the differences that are most important. Currently, a majority of countries prohibit extreme forms of genetic engineering, such as cloning or creating chimeras and any non-therapeutic interventions on a human embryo that seeks to alter the genetic patrimony of an individual.[110] Eugenic practices and sex selection, except in cases of sex-linked diseases, are also prohibited by many countries.[111] Therapeutic experimentation on human embryos, within the first fourteen days of development, is legal in many countries, although there are internationally recognized standards which must be met.[112]

Included in the following sections are legislation, recommendations, and proposed regulations from individual countries and international organizations.

A. European Organizations

1. European Parliament

The issues of cloning and other new biotechnologies have been addressed by the European Parliament since 1989. In that year, the European Parliament passed a resolution stating a concern that embryo research should be limited to only those circumstances where a benefit to the welfare of the endangered child can be demonstrated and any arbitrary experimentation should be prohibited.[113] Human cloning, industrial and commercial use of embryos, and trade in frozen embryos were also prohibited and must be subject to criminal penalties.[114] In another resolution that year, the European Parliament recognized that human life should be protected from the moment of fertilization and that waste embryos remaining from in vitro fertilization procedures should be eliminated.[115]

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110. Knoppers, *supra* note 105, at 329.

111. *Id.*

112. *Id.* at 340. The four conditions that research must meet are: 1) scientific validity as verified by a review committee; 2) the free and informed consent of the participants; 3) the balance of the risk-benefit ratio; 4) conformity of the research with the notion of public order. Provided that these conditions, the majority of countries, except for Germany, Denmark, Austria, and Norway, would allow therapeutic research on the human embryo.

113. Resolution on the Ethical and Legal Problems of Genetic Engineering, 1989 O.J. (C 96) 165, 169.

114. *Id.* at 170.

115. Resolution on Artificial Insemination, In Vivo, and In vitro Fertilization, 1989 O.J. (C 96) 171, 172.

The European Parliament further defined their recommended restrictions and expanded upon the procedures that it deemed to be prohibited in a resolution passed in 1996. Here, any form of manipulation on the human genome which modifies or seeks to modify the germ line, as well as any consumptive research on and production of human embryos for research purposes only must be banned by law.[116] Furthermore, developing tests in the future that may predict behavioral traits or genetic testing for disease, except for those circumstances in which there is currently effective treatment or preventive measures regarding that particular disease, must be strictly prohibited.[117]

2. European Commission

In 1994, the European Commission reconstituted its Group of Advisors on the Ethics of Biotechnology and instituted a mission whereby the ethical aspects of biotechnological experimentation within the European Union should be assessed and the potential implications that such activities would have on individuals and society identified.[118] In coordination with the European Parliament, the European Commission has denounced attempts to clone human beings and is considering whether to seek a strict moratorium on the level of the Council of Europe or the United Nations.[119]

Attempts to patent discoveries and knowledge in the area of biotechnology have also been addressed by the European Commission and the opinions handed down have denied patentability to the human body or any of its elements.[120] Specifically, the simple knowledge of the complete or partial structure of a gene and the human body, at any stage of development or constitution, does not constitute patentable elements.[121] On the other hand, patentability may be afforded to the identification of the function attached to a human gene if it offers new possibilities such as the production of new drugs, or if the intended use of the patent is sufficiently identified and specific.[122]

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116. Resolution on the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine, 1996 O.J. (C 320).

117. *Id.*

118. *Bioethics: Greens Call for Public Debate*, EUR. ENV'T, Mar. 15, 1994, § 48.

119. *European Union and European Parliament Denounce Human Cloning*, DEUTSCHE PRESS-AGENTUR, Mar. 11, 1997.

120. *Group of Advisors on the Ethical Implications of Biotechnology of the European Commission Opinion on the Ethical Aspects of Patenting Inventions Involving Elements of Human Origin*, 48 INT'L DIG. OF HEALTH LEGIS. 91, 92 (1997).

121. *Id.* § 2.2, 2.3.

122. *Id.* § 2.5.

3. European Union

The European Union, made up of twelve major European states, encompasses an economic dimension and has broad power to enact strict and precise regulations concerning industry and research. Working through the European Commission's Advisory Group on Ethics in Biotechnology, the European Union has sponsored recommendations which are to be issued at the end of May 1997.[123] Of the main issues discussed by the Group, the first is that the position to condemn human cloning is basically unanimous in European nations. Through a comparison of national legislative systems, bans of human cloning are in some countries expressly prohibited, while in others it is approached implicitly from other principles demonstrated in the law.[124] The cloning of Dolly has led to an increased awareness that an international agreement on the condemnation of human cloning is necessary.[125] A second issue discussed is in regard to animal cloning and its commercial applications. While the Group has stated that no commercial application has been applied to animal cloning, the feasibility of such an application is growing near.[126] The Group has expressed concern that the well-being of the animals and the ethical principles of animal protection must be reaffirmed with regard to the aspects of cloning.[127]

According to the joint European Parliament/Council of Europe decision of April 26, 1994, financing for germinal gene therapy, as well as research for human cloning, was prohibited by any Community.[128] While the Union was within their legal competence in prohibiting these acts, there are no penal or ethical prerogatives attached.[129]

4. Council of Europe

With a membership of forty countries, the Council of Europe has a focused participation in the issues of human rights. Beginning in 1990, the Council has adopted many policies and recommendations concerning the application of science and technology to the human genome. In that year, the Council adopted guidelines outlining the scope of the analysis into the

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123. *First Guidelines of Advisory Group on Ethics in Biotechnology at end of a Hearing with Parliamentary Experts and Interest Groups*, AGENCE EUROPE, Apr. 30, 1997.

124. *Id.*

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *First Guidelines*, *supra* note 123.

human genome in order to promote harmonious development in the European Community while pursuing scientific and technical excellence.[130] The goals of these guidelines include the encouragement of cooperation between European research facilities in furthering the development of existing technologies, while promoting the generation of new lines of research.[131] The overall objective of the program is to gain a better understanding of genetic functions and to fight against diseases arising from genetic variation, through the use of early diagnosis, prevention, and improvement of prognosis and therapy.[132] While the goals seem to allow for a broad range of experimentation to be conducted, some forms of research are specifically excluded. Any alteration of germ cells or any stage of embryo development with the aim of modifying human genetic characteristics in a hereditary manner is prohibited, as is somatic gene therapy, except in cases of somatic actual or potential medical applications.[133]

Many issues concerning research and experimentation were left unresolved by the decision in 1990. Among these issues are the rights that are afforded to the embryo and at what point should research on embryos be prohibited. A number of countries consider the embryo to be a human being at the time of creation and ban all nontherapeutic research, while others authorize research to be conducted until the fourteenth day of development.[134] Some countries permit the creation of embryos for research purposes, while others allow only nonviable embryos to be used.[135] The Council began addressing many of these issues, beginning with human cloning, in July of 1997. On July 1, the Council agreed to adopt a proposal prohibiting any act aimed at creating a genetically identical being, whether dead or alive.[136] This amendment to the Convention on Human Rights and Biomedicine will apply to only those who are signatories to the Convention, and at present time only twenty-two countries have agreed to their ban on human cloning.[137] Further discussion regarding this amendment is scheduled for September of 1997.

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130. Council Decision 90/395/EEC, 1990 O.J. (L 196).

131. *Id.* Preamble.

132. *Id.* § 4.1(Evaluation Criteria).

133. *Id.* § 4.4(2), (4), (5) (Evaluation Criteria).

134. Lenoir, *supra* note 106, 1260.

135. *Id.*

136. *Council of Europe Agrees to Ban Cloning of Humans*, DEUTSCHE PRESSE-AGENTUR, July 1, 1997.

137. *Id.*

Later, in July of 1997, the European Council adopted the Convention on Human Rights and Biomedicine. As a basis for this Convention, the interests and welfare of the human being shall prevail over the sole interest of society or science and the respect for individual integrity and the fundamental freedoms with regard to the application of biology and medicine is guaranteed.[138] Each party to the Convention shall conform their internal law to the provisions of the Convention, either by directly applying them in domestic law or by enacting the necessary legislation to give them effect.[139]

According to Chapter Four of the Convention concerning the human genome, only interventions undertaken for preventive, diagnostic, or therapeutic purposes are permitted.[140] Predictive testing of genetic diseases or to detect a genetic predisposition towards a genetic disease may be performed only for health purposes or scientific research linked to health purposes.[141] Developments in genetics now make it possible to detect those who carry specific genes for major single gene disorders,[142] and also those who are at risk of developing major disorders later in life.[143] Any intervention of the human genome which seeks to modify the genome of any descendants, modify genetic characteristics not related to a disease, or select the sex of the future child is prohibited, except for situations where a sex-related hereditary disease is present.[144]

As a general rule, scientific research in the fields of biology and medicine shall be carried out freely, subject to provisions ensuring the protection of the human being and the conditions set forth by the Convention.[145] The protection of persons undergoing research is expressed by conditions which must be met, including: there is no alternative of comparable effectiveness to research on humans, the risks which may be incurred by that person are not disproportionate to the potential benefits of the research, and the research project has been approved by a competent

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138. Convention on Human Rights and Biomedicine and Explanatory Report, Apr. 4, 1997, Art. 1, 2, 36 I.L.M. 817, 821 [hereinafter Convention on Human Rights].

139. *Id.* at 829, Art. 2(20).

140. *Id.* at 822, Art. 13.

141. *Id.* at 822, Art. 12.

142. *Id.* at 833, Art. 12(78). Examples of major single cell disorders that can be detected; cystic fibrosis, hemophilia, and Huntington's disease.

143. *Id.* at 834. Examples of disorders that may develop later in life; heart disease, cancer, and Alzheimer's disease

144. Convention on Human Rights, *supra* note 138, at 822, Art. 13, 14.

145. *Id.* at 822, Art. 15.

body after an independent examination of its aim and scientific merit.[146] The creation of embryos for research purposes is prohibited, but where domestic law allows for research on embryos in vitro, the law must also ensure adequate protection of those embryos.[147] Thus, while domestic law may allow research to be conducted on embryos, the Convention does mandate that no research be permitted after the fourteenth day of development.[148]

Lastly, the parties to the Convention shall provide judicial protection that is appropriate to prevent any unlawful infringement on the principles and rights set forth in the Convention.[149] Furthermore, the parties are to elicit public debate over the medical, social, economic, ethical, and legal issues that are relevant to these types of research. Nations may organize appropriate methods for encouraging public awareness of the fundamental questions raised.[150]

B. Individual European Countries

1. Germany

In what seems to be an effort to exorcize past atrocities, Germany has taken a hard line approach towards the issues of cloning and genetic experimentation. Under the German Constitution, an embryo does have the right to life, and causing the destruction of a human life, even if in the form of a nonviable fetus, is punishable by law.[151] Going farther than any other country in the prohibition against genetic technologies, Germany passed the Embryo Protection Law in 1990. Among the most specific legislation passed by any country, this law prohibits activities ranging from the cloning of humans and embryo research to improper uses of reproductive technologies. As was stated to the German Parliament by Friedrich-Adolf Jahn, the parliamentary state secretary in the justice ministry, "Because man is not the creator, he must content himself with being part of creation. Thus not all that is technically feasible is

146. *Id.* at 822, Art. 16.

147. *Id.* at 823, Art. 18.

148. Lenoir, *supra* note 106, at 1260.

149. Convention on Human Rights, *supra* note 138, at 823, Art. 23.

150. *Id.* at 824, Art. 28.

151. Elizabeth Ann Pitrolo, Comment, *The Birds, the Bees, and the Deep Freeze: Is There International Consensus in the Debate over Assisted Reproductive Technologies*, 19 HOUS. J. INT'L L. 147, 188 (1996).

allowed."[152] Violations of prohibited activities can vary from three to five years in prison and/or fines.

Specifically, one of the law's prohibitions goes directly at the issue of cloning human beings and imposes up to five years imprisonment, or a fine, for any person who artificially causes a human embryo to develop with the same genetic information as another embryo, fetus, or living or deceased person.[153] Other prohibitions aim at the manipulation of human genes by offering the same punishment to any person artificially altering the genetic information of a human germline cell, creating chimeras or hybrids, and artificially selecting the sex of an offspring, except in cases of serious gender linked diseases.[154] Research involving the artificial modification of the genetic information of a germline cell situated outside the body is allowed if there is no possibility of its being used for fertilization.[155]

In response to the research conducted in the United States and the development of Dolly in Scotland, Germany has called for international ban on all efforts to clone human beings. Subsequent to the human embryo splitting completed at George Washington University, Germany publicly denounced the experimentation and expressed great concern that these events should not be repeated in Europe.[156] Remembering the atrocities that resulted during the Nazi regime, Germany has been outspoken against any manipulation of human embryos. After the results in Scotland were made public, Germany again expressed dismay over the events and called for the prohibition against applying cloning technologies to humans.[157] In order to express the significance of banning this type of research, Germany has refused to sign any declaration or convention that does not include an unambiguous condemnation of human cloning.[158]

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152. Rolf Soderlind, *Germany Passes Law Against Surrogate Mothers and Human Cloning*, REUTER NEWS SERVICE - W. EUR., Oct 24, 1990.

153. Embryo Protection Law of 13 Dec. 1990, ch. 6 § 1(BGBI. I, 19 Dec. 1990, at 2746-2748), *reprinted in* 42 INT'L DIG. OF HEALTH LEGIS. 60, 62 (1991).

154. *Id.* ch. 5 S1, ch. 7, ch. 3

155. *Id.* at 62, ch. 5 S 4.

156. *Call to Halt Human Cloning*, PRESS ASS'N NEWSFILE, Oct. 26, 1993, at 000.

157. *German Scientists Join in Call for International Ban on Human Cloning*, THE WEEK IN GERMANY, May 9, 1997.

158. *Id.*; *See also supra* note 150. Germany abstained from voting on the Convention on Human Rights and Biomedicine for reasons including lack of protection for the handicapped.

2. France

Being a country who believes in advancing the progress of biotechnology in order to cure disease and disabilities, France has taken a somewhat different approach towards legislating scientific and medical research. Under the French Constitution, the rights of the individual extends not only to privacy and individual freedom, but also to an individual's right of access to social advantages.[159] On the other hand, the Constitution also justifies the state intervening into the affairs of science and medicine, through the regulation of medical practices and of gaining access to the biotechnological advances.[160] Therefore, the legislation that emerges from France expresses both the notions of individual liberty and freedom of research and that science must advance.[161]

In creating a bioethics bill, French legislators looked to satisfy both scientists and ethicists in limiting the areas that human embryo research may be conducted. The bill expresses regulations concerning the protection and respect of the human body, utilization of cells, organs and tissues, and research agenda. To begin with, the integrity of the human body may only be violated in the event of a therapeutic necessity of the person involved, although the genetic study of an individual's characteristics may be undertaken for scientific or medical purposes.[162] Any attempt to perform a eugenic procedure aimed at organizing the selection of persons or any alteration made to the genetic characteristics with a view towards modifying a person's lineal descent is subject to receiving a penalty of up to twenty years imprisonment. Among the procedures also prohibited by the bill and for the protection of the human embryo are using human embryos for industrial or commercial purposes and performing in vitro fertilization of human embryos for research or experimental purposes.[163]

Concern over the bioethics bill has emerged from both scientists and ethicists, stating that the language expressed in the bill does not give researchers clear guidance about what they can and cannot do.[164] Issues of preimplantation diagnosis and cloning still seem to be unresolved and under certain circumstances may still be allowed. To gain a clearer

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159. Lenoir, *supra* note 106, at 1250.

160. *Id.* at 1252.

161. *Id.*

162. Law No. 94-653 of July 29, 1994, J.O., July 30, 1994, No. 175, at 11056-11059, Art. 16(3), (10), *reprinted in* 45 INT'L DIG. OF HEALTH LEGIS. 453, 498 (1994).

163. *Id.* Div. 3 Art. 511-17, 511-18.

164. Axel Kahn, *Researchers Nervous About Bioethics Bill; France*, 263 AM. ASS'N FOR THE ADVANCEMENT OF SCIENCE 463 (1994) (statement by geneticist Axel Kahn).

understanding on what exactly is prohibited, the language used in French legislation needs to be more specific in order to prevent misuses and abuses of biotechnological advances.

3. Spain

Spain has enacted legislation aimed specifically at regulating assisted reproduction procedures and the use of human embryos in research in two laws passed in late 1988. Among the procedures expressly forbidden were the creation of human beings by cloning or other procedures directed to the selection of traits or the creation of human beings by cloning in any of its variants, or any other procedure capable of yielding several identical humans.[165] Creating pre-embryos from persons of the same sex, creating an individualized human in a laboratory, and employing genetic manipulation for military or any other purposes, in order to produce biological weapons are also specifically prohibited and considered very serious offenses.[166] The law does permit embryo research to be performed as long as it is focused on enhancing the embryo's viability or detecting hereditary diseases. Authorization for research on pre-embryos in vitro is permitted in situations where the research has a diagnostic, therapeutic or prophylactic purpose.[167] There are exceptions to these goals, including when the pre-embryo involved is non-viable or research can not be scientifically performed on animals.[168]

In the second law, passed in 1988, governing the issues of donation and use of human embryos. Research in genetic technologies using human genetic material may be performed for diagnostic purposes in respect of genetic or hereditary diseases, for therapeutic purposes mainly concerning sex selection in the event of sex-linked diseases, and for research purposes in which the study of DNA sequences of the human genome, their location and functions, as well as other research takes place.[169] Research is also permitted in the area of industrial purpose, which entail a preventive, diagnostic, or therapeutic characteristic.[170] Moreover,

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165. Law No. 35/1988 of Nov. 22, 1988 on Assisted Reproduction Procedures, B.O.E., 1988, 282, ch. 6 § 20(k), (l), *reprinted in* 40 INT'L DIG. OF HEALTH LEGIS. 1, 82 (1994). Seems to imply a prohibition of both twinning and nuclear substitution.

166. *Id.* ch. 6 § 20(o), (s), (v).

167. *Id.* ch. 4 § 15(2).

168. *Id.* ch. 4 § 15(3).

169. Law No. 42/1988 of Dec. 28, 1988 on the Donation and Use of Human Embryos and fetuses or their cells, tissues, or organs, B.O.E., 1988, 314, ch. 3 § 8, *reprinted in* 42 INT'L DIG. OF HEALTH LEGIS. 1, 66 (1989)

170. *Id.*

utilization of human gametes and of fertilized and developed ovules is permitted until the fourteenth day following fertilization.[171]

4. Switzerland

While there are currently no laws specifically prohibiting the use of cloning technology on human beings, Switzerland has taken steps to restrict the field of embryo research and infertility procedures. Dating back to 1987, the Swiss Health Council has set forth guidelines prohibiting any research to be conducted on human embryos and has restricted the storage of embryos for the duration of an individual in vitro fertilization procedure.[172] Also in 1987, any interventions on the genetic material of human cells was banned by law.[173] Furthermore, the misuse of and trade in embryos for pharmaceutical purposes has been prohibited.[174]

5. Norway

According to Norwegian legislation, any research on human embryos is strictly banned and criminal sanctions for research on fertilized eggs are available.[175] Although domestic research is banned, the use of embryo research, including cloning, conducted outside the country and brought into Norway for clinical use may not be necessarily prohibited.[176]

6. Sweden

Unlike other countries in Northern Europe, Sweden's current legislation would seem to allow research on embryos. This includes either those embryos left over from infertility treatments or ones created for research purposes.[177] Sweden prohibits the implantation of an egg fertilized outside the woman's body, unless, among other conditions, the egg is the woman's own and has been fertilized with her husband's or cohabitant's sperm.[178] No other domestic legislation involves embryonic procedures, thus the language of Law no. 711 leaves open the possibility that research

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171. *Id.* at 68.

172. Stuart Hornett, *Embryos and Europe: What Prospects for Harmonization*, 141 NEW L. J. 713, 715 (1991).

173. Directive of Feb. 2, 1987 on in vitro fertilization and embryo transfer for the treatment of human fertility, 39 INT'L DIG. OF HEALTH LEGIS. 1, 82 (1988).

174. *Id.*

175. Hornett, *supra* note 172, at 715.

176. *Id.*

177. *Id.*

178. Law No. 711 of June 14, 1988 on fertilization outside the human body, 40 INT'L DIG. OF HEALTH LEGIS. 1, 93 (1989).

on human embryos, as well as cloning, is permissible. Nonetheless, those who breach this law, through habitual offenses or seeking commercial gain, shall be liable to a fine or a minimal prison sentence.[179]

7. Denmark

While there is no specific legislation covering genetic procedures such as cloning, Denmark has established a biomedical research ethics council which does have an underlying philosophy that human life begins at fertilization.[180] Under this authority's recommendation, harmful embryo research should be prohibited and embryos should not be created for research purposes only.[181] Until the creation of specific legislation, the ethics council has imposed a moratorium on embryo research.[182] Denmark does permit fertilized human oocyte research to be performed as long as it is accordance with the established guidelines.[183]

8. Other European Countries

Other individual countries have passed some types of legislation with regard to new genetic engineering procedures, but in most cases they are recommendations set forth by ethical and medical organizations and government-sponsored councils. In Greece, legislation has been passed in which in vitro fertilization and embryo freezing has been banned.[184] Recommendations suggested in Italy proposes that all embryo research be subject to criminal penalties.[185] Lastly, in the Netherlands proposals permitting embryo research in limited circumstances have been suggested. Following the recommendations handed down by the Council of Europe's Commission of Experts on Progress in the Biomedical Sciences, the creation of embryos for research purposes should be banned and allowing research on surplus embryos only in limited situations.[186]

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179. *Id.*

180. Hornett, *supra* note 172, at 714.

181. *Id.*

182. *Id.*

183. Pitrolo, *supra* note 151, at 186.

184. Hornett, *supra* note 172, at 714.

185. *Id.*

186. *Id.*

C. Commonwealth Countries

1. Great Britain

The creation of Dolly, achieved by scientists in Scotland, exposes the significance of how important unambiguous and detailed legislation is to protect against abuses of genetic technology. It can also be said that the success in Scotland is another example of howquickly science can progress and how difficult it is for the legislature to keep up. Legislation in Great Britain prior to Dolly, while quite liberal in many respects, was thought to prevent against the cloning of human beings. But if success in cloning humans was achieved by utilizing the same techniques as those used in Scotland, it would not be considered to fall under current legislation.

Legislation concerning research on embryos and the subsequent development of them is focused in the Human Fertilization and Embryology (HFE) Act of 1990. The Act establishes the HFE Authority in order to regulate infertility treatments and to grant licenses to conduct embryo research.[187] Under the law, an embryo is not treated as having a right to life and is not afforded the same status as a human being.[188] Therefore, the Authority is permitted to grant licenses that allows for research to be conducted on human embryos.[189] For example, a person is prohibited from creating an embryo for research, except if in pursuance of a license.[190] Other activities which are permitted are the destructive research on surplus embryos and those created specifically for research,[191] destruction of embryos which are kept in storage in excess of statutory limits,[192] and the screening out of defective embryos prior to implantation in a woman.[193] There are situations in which the Authority is not permitted to issue a license, including keeping or using an embryo after the appearance of the primitive streak,[194] or altering the genetic structure of any cell while it forms part of an embryo, except in situations in which it is

187. Human Fertilization and Embryology Act, 1990, § 5, 11 (UK).

188. Pitrolo, *supra* note 151, at 172.

189. Human Fertilization and Embryology Act, *supra* note 187, § 11, 12.

190. *Id.* § 3(1)(a).

191. *Id.* Sched. 2 § 3.

192. *Id.* § 14(1)(c). Current statutory storage period for embryos is 5 years.

193. *Id.* Sched. 2 § 1(d).

194. *Id.* § 3(3)(a) - According to the HFE Act., section 3(4), the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored.

permitted.[195] Another prohibited activity, and one which has caused the greatest concern over insufficient legislation, is the replacing of a nucleus of a cell of an embryo with a nucleus taken from the cell of any person, embryo, or subsequent development of an embryo.[196] An embryo is defined by the Act as a live human embryo where fertilization is complete and references to an embryo include an egg in the process of fertilization.[197] Thus, the legislation is seems to suggest that cloning by nuclear substitution is prohibited and cloning by embryo splitting is permitted with a license from the HFE Authority.

The creation of Dolly consisted of fusing an adult sheep fetal cell with an enucleated egg cell and implanting the egg into a third ewe. Thus, it was not an embryo in the true biological sense and would not be considered an embryo under the definition set forth in the Act. Furthermore, the development of the artificially created cell did not consist of a gamete, an egg or sperm, nor did it undergo fertilization, fusion of an egg and sperm, allowing it to escape the definitions of the Act.[198] Based on this, the application of this technique to clone human beings would not be prohibited by the cloning provisions currently in place. This same technique may also elude the prohibition against the altering of the genetic structure of a cell while it forms part of an embryo, because the cells utilized by the researchers in Scotland would not fall within the definition of an embryo defined in the Act.[199]

As is shown by the events in Scotland, legislatures in every country must be particularly specific when drawing up appropriate legislation. With the ever increasing pace of discovery in the field of genetic research, laws banning potentially detrimental activities must be able to encompass not only what is currently feasible, but also what will be feasible in the future. In Great Britain, a rewording of the definition of an embryo and the adding of prohibitions against the techniques utilized in Scotland is necessary to prevent unwanted abuses. An example of a possible embryo definition would be one which reads "embryo means a live human embryo where fertilization is complete or where a cell has been modified, created, or altered such that it has the potential to develop into an embryo or foetus."[200]

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195. Human Fertilization and Embryology Act, *supra* note 187, Sched. 2 §§ 3,4.

196. *Id.* § 3(3)(d).

197. *Id.* § 1(1)(a), (b).

198. Sharon Korek, *Following Dolly*, 147 NEW L. J. 428, 429 (1997).

199. *Id.*

200. *Id.*

2. Australia

Because of the lack of constitutional power in the federal government to intervene in reproductive technologies, individual Australian states are free to enact their own legislation.[201] Thus, achieving uniform regulations remains a primary goal in Australia, in order to prevent *border hopping* from occurring. Currently, human cloning is only prohibited in Victoria and Western Australia, while in the other states the issue remains unclear. In these two states, an embryo receives a status, while not that of *personhood*, in which it deserves more respect than an entity created solely for research purposes.[202] The remaining states follow the guidelines set forth by the National Health and Medical Research Council, which technically allows cloning, but recommends that it is ethically unacceptable.[203]

The Human Reproductive Technology Act of Western Australia considers the only justification for fertility procedures, to be conducted outside the woman's womb, is for assisting the couple who donated the genetic materials to have children.[204] While recognizing that certain experimentation and research is not harmful and in some cases may be allowable, fertilizing an egg for other than implantation purposes is not approved.[205]

Victoria has enacted specific legislation directed at cloning and embryo research. Under the Infertility Treatment Act of 1995, it is Parliament's intention that human life should be preserved and protected and the welfare of any person born as a result of fertility procedure is paramount.[206] In response to this intention, Victoria has banned outright, certain procedures such as, cloning[207], using embryos or zygotes removed from the body,[208] and mixing gametes, zygotes, or embryos from more than one person.[209] Furthermore, many provisions of the Act place restrictions on attempts to conduct embryo research when performed outside the woman's body. Among the initial restrictions are approval of a licensing

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201. Judy Friend & Richard Ogier, *Gap in Australian Laws on Cloning*, (visited Sept.25,1997) <http://www.ozemail.com.au/search/283U2.html>.

202. Pitrolo, *supra* note 151, at 176. (Waller Committee recommendations).

203. Friend, *supra* note 201.

204. Human Reproductive Technology Act, 1991, (Austl.).

205. *Id.*

206. Infertility Treatment Act, 1995, § 5(1)(a), (b) (Austl.).

207. *Id.* § 47.

208. *Id.* § 44.

209. *Id.* § 46.

authority on the research to be performed and a following of the regulations that they provide.[210] Research aimed developing an embryo to syngamy and destructive research are not to be approved by the Authority.[211] Moreover, research involving embryos is not permitted for embryos that are unfit for implantation or if the embryo is transferable, research is not permitted if the particular research would deem the embryo untransferable or harm the embryo.[212]

Legislation in Victoria also restricts certain procedures with regard to genetic manipulation and offers penal provisions for performing prohibited experimentation. Alteration of the genetic constitution of a gamete used to form an embryo or zygote or to be used in a fertility procedure is prohibited, as well as, altering the genetic, nuclear, or pro-nuclear constitution of an embryo or zygote.[213] Exceptions do exist should the alteration of somatic cells be necessary for therapeutic purposes.[214] Lastly, alteration to select the sex of a child is prohibited except in situations where it is necessary to avoid the risk of transmission of a genetic abnormality or disease to the resulting child.[215]

3. New Zealand

Although there has been no reports of any activity in the area of cloning, New Zealand has begun to address this issue as well as others concerning genetic engineering. Currently, the only regulation on the matter is that any new medical procedure must gain approval before an ethics committee.[216] Admittedly behind other commonwealth countries, such as Australia and Great Britain, proposed legislation is seeking to ban certain unethical practices including, human cloning, commercial surrogacy, and the sale of embryos and gametes.[217]

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210. *Id.* § 22, Part 8

211. Infertility Treatment Act, 1995, §§ 25, 26 (Austl.).

212. *Id.* § 24.

213. *Id.* § 39.

214. *Id.*

215. *Id.* § 50.

216. Helen Bain, *New Bill to Ban Cloning of Humans*, THE DOMINION (WELL.), Mar. 14, 1997, at 2.

217. *Id.*

D. North America

1. United States

Any effort to condemn the cloning or genetic manipulation of human beings on a world wide basis is meaningless unless the United States agrees to abide by the legislation. The United States has taken a leading role in the exploitation of genetic technology, being the initiator of the Human Genome Project and spending an unprecedented amount of money funding research.[218] But, because of limitations encountered within the United States Constitution, scientists conducting genetic research have less governmental intrusion, then would be encountered in other countries. The lack of federal regulations concerning privately funded institutions, because of the absence of constitutional power to govern assisted reproductive technologies,[219] has enabled private institutions to remain unconstrained when initiating research. Currently, the United States does not have any laws prohibiting cloning procedures, although some state and federal laws and policies, discussed later, may have some application. The constitutional and legal arguments, as well as the moral and ethical issues, that are in some respects unique to American society and thus constrain legislative efforts, will also be discussed more completely under their respective headings.

The lack of federal regulation over genetic technology first came to the public's attention when in 1993, researchers at George Washington University successfully split a human embryo and allowed partial development to occur.[220] Negative reaction condemning the experiment was expressed from scientists, ethicists, and the general public from the United States, as well as around the world. No legislation was passed in response to the success, and research resumed at its normal pace, without interference. With the announcement of the creation of Dolly in 1997, issues of cloning and genetic research once again came to forefront of public debate.

President Clinton, in response to news from Scotland, announced that effective March 4, 1997, no federal agency may support, fund, or

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218. Smith, *supra* note 96, at 3. An estimated $3 billion will be spent on the Human Genome Project.

219. Pitrolo, *supra* note 151, at 201. Overshadowed by constitutional protections, jurisdiction regarding assisted reproductive technologies falls within the realm of state governments.

220. *See* discussion *infra* Part II Advancements in Cloning Technology.

undertake cloning activities.[221] While previously only funding aimed at research on human embryos was federally restricted, loopholes became apparent and President Clinton's announcement further restricted federal funds from being used in any way towards research into the cloning of human beings.[222] Describing the issue as one which is not only a matter of scientific inquiry, but of morality and spirituality as well, the President urged a voluntary moratorium to the entire scientific and medical community, every foundation and university, and every industry that supports work in this area, to follow the federal government's example.[223] The moratorium would consist of abandoning all research concerning the cloning of humans until an appointed National Bioethics Advisory Commission and the nation as a whole, has had a chance to debate the all the possible implications.[224]

In June of 1997, the National Bioethics Advisory Commission (NBAC) published their report and recommendations on the issue of cloning human beings.[225] Within the report, the NBAC acknowledges the fact that regulations concerning private institutions is basically nonexistent. In effect, only those institutions who conduct research with the aid of federal funding or who have executed multiple assurance agreements with the federal government are subject to the regulatory provisions.[226] As such, it is only these institutions which must adhere to the prohibition against the cloning of humans, as well as the restrictions governing the use of human subjects in research.[227] The report also explores the potential benefits that may be derived from acquiring cloning technology, such as in the areas of medical research and agriculture, but because of their potential use in humans, these activities must be currently restricted.

Among the recommendations handed down by the NBAC are that the current moratorium on the use of federal funding to support cloning activities be continued and that private institutions should voluntarily adhere to the moratorium because at this time, an attempt to clone a human

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221. *Remarks By President Clinton Announcing the Prohibition on Federal Funding for Cloning of Human Beings*, FED. NEWS SERVICE, Mar. 4, 1997, at White House Briefing [Hereinafter Remarks by President Clinton].

222. *Id.*

223. *Id.*

224. *Id.*

225. *Report and Recommendations of the National Bioethics Advisory Commission* (final draft June 6, 1997) <http://www.washington-fax.com/pass/doc-sets/bioethics/nbac/index-nbac-rep0697.shtml> [hereinafter NBAC Report].

226. *Executive Summary, NBAC Report* (visited Sept. 25, 1997) <http://www.washington-fax.com/pass/doc-sets/bioethics/nbac/nbac-rep0697-0-05.shtml>.

227. *Id.*

being would be irresponsible, unethical, and unprofessional.[228] Therefore, the cloning of a human being, no matter the reasons for or the source of funding, should at this time be prevented and prohibited. Further recommendations call for a sunset clause to be inserted in any proposed federal or state legislation that would provide for review period after three to five years in order to reexamine whether a further prohibition is necessary.[229] If a legislative ban is not enacted, or once enacted is subsequently lifted, all efforts to utilize somatic cell nuclear transfer to create a child should be preceded by controlled research governed by independent review and standards relating to the protection of human subjects.[230]

According to the NBAC, the language incorporated into any legislation or regulatory action must be carefully chosen in order to protect against interference with permitted areas of scientific research.[231] Regulations must not impede upon the areas of animal cloning, cloning DNA sequences and cell lines, and those fields of research which have already provided important scientific and biomedical advances.[232] The NBAC further recommends that the United States should cooperate with the international community to enforce those aspects which are common to their respective cloning policies.[233] An example of this was accomplished at the G7 Summit of Economic Countries in June of 1997, in which the heads of states from member countries endorsed a worldwide ban on cloning humans.[234]

Federal legislation has been proposed in Congress which place restrictions on the use of federal funds for research into human cloning technology. The Human Cloning Research Prohibition Act, which proposes to deny the use of any federal funds to conduct or support any research that involves producing a human clone through the use of a human somatic cell, was introduced to the House of Representatives.[235] A similar bill was submitted in the Senate, which seeks the same ban on the use of federal funds and goes on to further define the prohibition on

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228. *Recommendations, NBAC Report* (visited Sept. 25, 1997) <http://www.washington-fax.com/pass/doc-sets/bioethics/nbac/nbac-rep0697-0-06.shtml>.

229. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

234. *Hearings, supra* note 20 (G7 member countries - U.S., Japan, Germany, England, France, Italy, and Canada).

235. *Id.*

cloning as the "replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal, and newborn stages into a new human individual."[236]

Legislation related to genetic and fertility research, previously enacted, may have some application to the prohibition on human cloning. The Fertility Clinic Success Rate and Certification Act of 1992 requires that clinics using assisted reproduction techniques be federally monitored.[237] This act is designed to cover all laboratories and treatments that involve the manipulation of human eggs and embryos.[238] During the 1980's, fertilization clinics became quite successful in the absence of any federal regulation. Currently, at least ten fertility clinics located in the United States have the technology to conduct somatic cell nuclear transfer experimentation.[239] According to reports, a Wisconsin company, ABS Global, has already claimed to have improved upon the techniques used in Scotland, by creating cow embryos from the skin, bladder, and udder cells of an adult cow.[240] To further increase the concern over fertility clinics, no professional society in the infertility field has publicly expressed agreement to the proposed moratorium against cloning technology, unlike the American Medical Association and other organizations in the medical field.[241]

Another area of related federal legislation is concentrated in the field of patents. According to the Transgenic Animal Patent Reform Act of 1988, human beings are not included in patentable subject matter.[242] Unfortunately, no definition is included in the Act and problems may occur in determining what genetic material is considered to constitute a human being.[243] One year earlier, non-naturally occurring nonhuman multi-cellular living organisms, including animals, was determined by the United States Patent and Trademark Office to be subject matter that is patentable.[244] This, as expected, created an uproar among theologians and

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236. *Proposed Legislation, § 368, NBAC Report* (visited Sept. 25, 1997) <http://www.washington-fax.com/pass/doc-sets/bioethics/nbac/nbac-rep0697-5-12.shtml>.

237. *Executive Summary*, *supra* note 226.

238. *Id.*

239. *Id.*

240. Wills, *supra* note 43.

241. *NBAC Report*, *supra* note 2265.

242. George P. Smith, II, *Toward an International Standard of Scientific Inquiry*, 2 HEALTH MATRIX 167, 180 (1992).

243. *Id.*

244. *Id.*

critics, who claimed that animals and other heavenly created creatures will be equated as products manufactured for the marketplace, and not as sentimental beings.[245]

Individual states have also begun to propose legislation concerning cloning and related technologies. Alabama has taken the largest step, proposing legislation that bans the use of governmental funds for any research using cloned cells or tissues.[246] Missouri and Maryland have introduced bills seeking to ban the use of governmental funds for cloning an entire individual.[247] Bills that prohibit the cloning of an entire individual, regardless of the funding source have proposed in some states including, Alabama, California, Illinois, New Jersey, New York, North Carolina, Oregon, and West Virginia.[248] Florida and California have bills proposed that explicitly ban any research using cloned cells or tissues.[249] Lastly, bills that might unintentionally ban research using cloned cells or tissues have been introduced in South Carolina and New York.[250]

2. Canada

Canada has taken broad steps through recommendations and criminal sanctions in order to restrict the permissible circumstances in which certain genetic technologies may be used. As early as 1993, recommendations were set forth that banned any research utilizing human embryos that were focused on cloning technology, pre-natal sex determination for other than therapeutic reasons, and for establishing a commission to oversee fertility laboratories and other clinics involved in fertility research.[251]

In 1995, Health Canada expressed additional recommendations regarding genetic technologies. According to these newer recommendations, human embryo research should only be allowed when approved by a National Regulatory Body. This does allow many procedures to still be undertaken and does not specifically prevent any procedure from being performed. Among the guidelines presented for the regulatory body to follow in selecting which experiments may be performed on human embryos are that it is necessary for the improvement of the human condition, inquiry into using animal or non-human models

245. *Id.*

246. *Proposed Legislation*, *supra* note 236.

247. *Id.*

248. *Id.*

249. *Id*

250. *Id*

251. Pitrolo, *supra* note 151, at 182.

has been exhausted, and the research is of the highest scientific quality.[252] Viable human embryos may be used but only when a compelling case is made that non-viable embryos cannot be successfully employed.[253] Any research that is permitted on human embryos may not be performed ex utero later than fourteen days after fertilization.[254] The regulatory body may also consider permitting the fertilization of human ova for research purposes only, should the potential benefits to society or future offspring require that the experimentations occur.[255] Human cloning, chimeras, as well other forms of experimentation are prohibited without the regulatory body's explicit approval, and in the case that a regulatory body is not formed, these types of experiments are specifically banned.[256]

In 1996, Canada introduced criminal sanctions in order to prevent many of the new genetic technologies from being performed. Under the Human Reproductive and Genetics Technologies Act, penalties of performing these outlawed practices will range from prison terms of up to ten years and/or fines to a maximum of $500,00 Canadian.[257] Among the areas of research to be criminalized are; human embryo cloning, germline alteration, research involving maturation of sperm or eggs outside the human body, the creation of embryos for research purposes only, and any research conducted on embryos later than fourteen days after fertilization.[258]

E. Asia and Japan

1. Japan

Currently, Japan does not have any specific legislation regarding cloning or the manipulation of human embryos. Scientists proceed on the basis of their own conscience and set of morals.[259] Guidelines concerning

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252. *Final Report of the Multidisciplinary Discussion Group on Embryo Research assembled by Health Canada in 1995*, 48 INT'L DIG. OF HEALTH LEGIS. 131, 229, (1997).

253. *Id.* at rec.4.

254. *Id.* at rec.3. Follows internationally accepted standards.

255. *Id.* at rec.10.

256. *Id.* at rec.11, 12. Among the research prohibited in the absence of a regulatory body are; human cloning, chimeras, production of interspecies embryos, and transgenic human embryos.

257. Wayne Kondro, *Canada gets tough with Reproductive Technologies*, THE LANCET, June 22, 1996 (discussing the June 14, 1996 Human Reproductive and Genetics Technologies Act).

258. *Id.*

259. *Analysis: Cloning Reports, Reactions Ripple Back to Japan*, ASIA PULSE, Mar. 7, 1997.

the manipulation of human embryos have been released by the Japan Society of Obstetrics and Gynecology, but the research conducted in government-funded and private sector laboratories are still without any clear cut regulations.[260]

Although the Education Ministry has decided, for the present time, not to allocate funding towards research on cloning human beings through the use of human tissues because of ethical issues, knowledge concerning the legal responsibilities of cloning research are still unknown.[261] No laws, regulations, moratoriums, or other restrictive measures regarding the research of cloning human beings are currently being considered by the Education Ministry.[262] In the area of animal cloning, Japan is highly advanced and the Education Ministry does plan to continue the funding this type of research. Utilizing embryo splitting techniques, universities in Japan has been successful in the cloning of farm animals and mice, but currently, they have not achieved any success in the cloning mammals.[263]

2. Hong Kong

Scientific research in cloning is basically a self regulating technology with no prohibitions and the subject has not been addressed in the country's courts or legislature.[264] Public concern, in respect to cloning technology, is focused on the well-being of the resulting children and the effects on family relationships.[265] In 1992, the Committee on Scientifically Assisted Human Reproduction published recommendations, attempting to answer these concerns, with some focused on research in this area.[266] Among the recommendations are that guidelines should be constructed concerning what is allowable in embryo research.[267] Included in these guidelines should be a prohibition that no embryo should be created deliberately for research and that no research should be allowed following the fourteenth day after fertilization.[268] Furthermore, standards regarding

260. *Id.*

261. *Ministry Decides not to Fund R&D on Cloning Humans*, JAPAN ECON. NEWSWIRE, Mar. 7, 1997.

262. *Id.*

263. *Cloning Reports*, *supra* note 259.

264. Pitrolo, *supra* note 151, at 193.

265. *Id.*

266. *Id.* at 194.

267. *Id.*

268. *Id.*

storage of gametes and embryos need to be set forth and any commercial surrogacy should be prohibited.[269]

3. China

Unlike most other countries, China has taken a very conservative approach on the issue of cloning humans, as well as cloning all other life forms. The Chinese Academy of Science has banned human cloning and recommended that guidelines regulating animal cloning be established and the responsibilities and rights of scientists be set forth.[270] Evaluation of the legal and ethical concerns of animal cloning should be accomplished by a newly created national body.[271] The Academy of Science believes that danger to the environment and ecological hazards may occur through any application of cloning technologies to any living species.[272] Traditional societal beliefs still exhibit a reluctance to accept children born through artificial insemination and in vitro fertilization procedures.[273]

4. Malaysia

Believing that it would against God's plan to have multiple clones of an individual existing at the same time, Malaysia has officially prohibited the cloning of human beings.[274] Although the cloning of humans is banned, the government will allow the cloning of certain animals to continue under conditions such as, reproducing quality livestock or saving an endangered species.[275]

F. Middle East

Islamic religious experts and scholars at a meeting of the Islamic Educational, Scientific, and Cultural Organization has recommended a prohibition of cloning research on human beings, but have accepted the cloning of animals and plants.[276] Although these recommendations are not a final *fatwa*, religious ruling, and until the *Sharia,* Islamic law, allows the technology of cloning humans to be explored, Muslim countries are urged

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269. *Id.*

270. *China Bans Human Cloning*, DEUTSCHE PRESSE-AGENTUR, May 13, 1997.

271. *Id.*

272. *Id.*

273. Pitrolo, *supra* note 151, at 184.

274. *Malaysia Bans Human Cloning*, DEUTSCHE PRESSE-AGENTUR, Mar. 18, 1997.

275. *Id.*

276. *Islamic Organization Recommends Human Cloning Ban* (visited Sept. 23,1997) <http://www.d-b.net/dti/970618casablanca.txt>.

to adhere to the ban.[277] In anticipation of foreign intrusion into Islamic countries, recommendations emerged that call for governments to enact the necessary legislation to prohibit foreign involvement in human cloning research.[278] The Organization based their recommendations on the belief that the direction that this technology is headed is unsafe and has immoral objectives.[279]

Other countries in this region have expressed opinions regarding embryo research and cloning technology. Israeli law may allow research on human embryos, but have stated that they are against cloning procedures.[280] Liberally minded in the area of fertility treatment, in vitro procedures for infertile couples are permitted and encouraged and because embryos are not considered living human beings until being born, under Rabbinic law, they are considered only as property.[281] In an opposite direction, the pro-Iranian Hezbollah faction has expressed an acceptance of cloning procedures. According to Sheikh Mohammed Hussien Fadallah, the spiritual guide of the Hezbollah, these scientific procedures have been discovered because God has allowed it to happen, and should therefore not be seen as an attempt to intervene in divine creation.[282] Furthermore, the Ayatollah Nasser Makarem-Shirazi, a major figure in the ultra-strict Islamic clergy of Iran, believes that human cloning will happen and that the clergy should begin studying the technology in order to be better suited to cope with the potential problems that may occur.[283]

G. South America

Argentina is one of the few South American countries that have entered into the bioethical debate of genetic technologies. While they currently do not address the cloning issue, recommendations have been presented that prohibits experimentation on embryos and genetic manipulation is allowed only for therapeutic reasons.[284] Sex selection in embryos is also prohibited except in situations where genetic disorders may

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277. *Id.*

278. *Id.*

279. *Id.*

280. *Hezbollah Mentor Says "God Allowed" Cloning*, DEUTSCHE PRESSE-AGENTUR, Mar. 13, 1997.

281. Pitrolo, *supra* note 151, at 195.

282. Hezbollah, *supra* note 280.

283. *Islamic Leader Braces Clerics for a Future with Human Cloning*, BIOTECHNOLOGY NEWSWATCH, Oct. 6, 1997, at 3.

284. Pitrolo, *supra* note 151, at 180.

be prevented.[285] The Senate Commission has also expressed that fertility procedures should only be allowed for infertility problems and not as an alternative means for achieving a pregnancy.[286]

H. World Organizations

1. The Vatican

From as early as 1987, the Vatican has publicly expressed concern and condemnation towards any technology aimed at assisted fertilization and cloning procedures. The belief that any non-therapeutic experimentation and freezing of embryos offends the dignity of fetal human life, the Vatican has urged countries to ban these procedures.[287] Reports of the experimentation conducted at George Washington University, prompted the Vatican to publicly condemn the scientists and conclude that the research was not justified and defied all legal barriers.[288] While understanding the importance of the genetic research, concern that a lack of respect for human dignity and the potential treatment of children as products of technology is overriding in their disapproval of genetic experimentation.[289] Upon learning of the success of researchers in Scotland, the Vatican has again become outspoken, calling for all efforts to clone human beings to be banned. The Church has expressed concern that psychologically cloned humans would be harmed by being constantly aware of a "real" or even "virtual" presence of his other(s).[290]

2. World Health Organization

The World Health Organization (WHO) is a multinational organization charged with addressing national and international disparities in health standards.[291] In considering the ethical implications of cloning and genetic technology, the Organization has recently held that, because of

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285. *Id.*

286. *Id.* at 181.

287. *Vatican Condemns American Cloning of Human Embryo*, AGENCE FRANCE PRESSE, Oct. 25, 1993.

288. *Id.*

289. *Id.*

290. *Pontifical Panel says Souls are Unclonable* (visited Sept. 23,1997) <http://www.d-b.net/dti/970624vatican.txt>.

291. *WHO Condemns Cloning of Humans as Ethically Unacceptable*, DEUTSCHE PRESSE-AGENTUR, May 14, 1997. Currently there are 191 member nations involved in the WHO.

respect for human dignity, the application of cloning research for the replication of humans is ethically unacceptable.[292] While the group realizes that there is a freedom to access the benefits of ethically accepted scientific progresses, necessary guidelines and safeguards must be put forth in national and international legislation. Among the forms of experimentation that are regarded as ethically unacceptable are; human cloning, alteration of the germ-cell genome, interspecies fertilization, and the creation of chimeras.[293] The WHO's resolution is not intended to prohibit all forms of cloning and some applications are acceptable.[294] The recommendations of the WHO are to be used as a starting point for an international public debate and individual countries are urged to enact conforming legislation on the domestic level.[295]

During the 50th World Health Assembly meeting in Geneva, delegates adopted a resolution affirming the views of the WHO and declaring that the cloning of human beings is ethically unacceptable and contrary to human morality and dignity.[296] Because of unprecedented ethical implications that cloning and the more extreme forms of genetic experimentation possess, development in genetic research must be carefully monitored.[297] Further assessment of international reactions to the legal aspects involved with cloning are to be discussed at the 1998 World Health Assembly.[298]

VI. DEBATE: MEDICAL ISSUES

The benefits that can be potentially achieved through cloning and genetic research, medically speaking, are significant and could produce an overall healthier society. In the fight against serious genetic diseases, these technologies could prove pivotal in their prevention and possible extinction. Areas of research, including disability prevention, organ transplant, infertility, and aging, can all be aided by knowledge in these

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292. *WHO Director-General Condemns Human Cloning*, (visited Sept. 26, 1997) <http://www.who.ch/press/1997/pr97-20.html>. Human reproduction should not be confused with human replication.

293. *Id.*

294. *Id.* The cloning of human cell lines is routine procedure is used for research on curing diseases such as cancer. Animal cloning also offers opportunities to advance biomedical research on diagnosis and treatment of diseases affecting human beings.

295. *Id.*

296. *WHO States its Position on Cloning in Human Reproduction*, (visited Sept. 26, 1997) <http://www.who.ch/press/1997/97wha9.html>.

297. *Id.*

298. *WHO Adopts Resolution Against Cloning Humans* (visited Sept. 23, 1997) <http://www.d-b.net/dti/970516who.txt>.

fields. In order to accommodate both the proponents and critics of genetic research, a balancing must occur between the goals of achieving an improved and healthier society and the protection of an indeterminable amount of embryos that will be destroyed through experimentation.

Many of the arguments supporting the continuation of cloning research come from those in the infertility field. Through cloning technology, couples who before had to rely on sperm or egg donors, can now use their own DNA for the offspring. For couples who are no longer fertile, they may wish to clone the DNA of a previous child or should a child die prematurely, their DNA can be replicated to give birth to another child. With the process of blastomere separation, a woman going through an in vitro fertilization procedure can elect to split the embryo and cyropreserve those embryos not necessary for achieving pregnancy. This will protect the woman from having to repeat potentially harmful fertilization treatment. Furthermore, regulations regarding cloning technology may in effect restrict otherwise legitimate genetic testing. For example, embryos used in IVF procedures that are determined to be carriers of certain diseases, such as cystic fibrosis, may be disregard in order to implant healthy and viable embryos.[299]

The search for treatments with brain and nervous system damage can also be aided by research using human embryos. Embryonic stem cells, because they are undifferentiated and can develop into almost any type of cell in the body, could be used to replace the damaged cells.[300] This undifferentiated status, along with their fast development, enables these stem cells to evade an attack by a person's immune system.[301] The large amount of these cells that would be needed to repair damage would most likely make cloning a necessity. Another area for a potentially beneficial use of genetic technology is in the field of cancer research. Because cancer cells develop at approximately the same rate as embryonic cells, scientists, through embryo research, may be able to slow down or even prevent the spread of cancer.[302]

Bone marrow transplants and skin graphs could each be performed easier with the help of cloning technology. A cryopreserved embryo can be implanted and allowed to develop in order to procure transferable matter.[303] With improved technology, an embryo may not even have to be

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299. Shari Roan, *In Our Own Image*, L.A. TIMES, Apr. 29, 1997, at A13.

300. *Human Cloning Techniques, supra* note 30.

301. *Id.*

302. *Id.*

303. *Id.*

brought to full term in order to be useful.[304] Lastly, the prevention of miscarriages due to chromosomal imbalances may also be improved.[305] Current figures estimate that over fifty percent of miscarriages occur from these imbalances and through genetic screening and experimentation, avoidance of this trauma may be possible.[306]

For those individuals that are against permitting cloning and other genetic technologies to be researched, equally persuasive arguments are expressed. First, there is not much justification in permitting thousands of embryos to be manipulated through experimentation and ultimately destroyed for the benefit of producing a single cloned person.[307] While the embryo is not afforded protection equal to that of an adult human, many people feel that it should still receive a special status. An unsettling feeling emerges from the knowledge that a significant number of embryos, that have the potential to achieve life, will be sacrificed in the pursuit of science. Critics further argue that the increase in the rate of achieving a successful pregnancy by splitting embryos during an IVF procedure is a misleading figure and is due to the genetic heterogeneity of the transferred embryos and not to increased amounts.[308]

Fear of eugenic procedures and memories of past horrors entails another reason to prohibit such research from being conducted. The ability to manipulate the genetic foundation of man and to literally control creation is a power which if misapplied could result in the loss of freedom, individuality, and human dignity, for the present, as well as future generations. Logic dictates that if the ability to control genetic characteristics is developed, a so-called positive eugenic program will emerge. Positive eugenics selects those traits which are most beneficial and encourages those with the finest genetic profiles to breed. A predictable outcome of this would entail the increased selection of particular traits and thus, a large scale effort to produce similar or identical types of humans. Nature's process of natural selection is suspended and the reality of a "Brave New World" is upon us.

The pivotal questions posed to protect against abuses is therefore, who will control the process, and how will the selection of genetic characteristics be chosen. The answers are potentially as disturbing as the questions asked. Under governmental control, fears of a manufactured

304. *Id.*

305. Conte, *supra* note 69, at 440.

306. *Id.*

307. Pirtrolo, *supra* note 151, at 199

308. Debra Feuerberg Duffy, *To Be or Not to Be: The Legal Ramifications of the Cloning of Human Embryos*, 21 RUTEGERS COMPUTER & TECH. L.J.189, 216 (1995).

society, much like "A Brave New World,"[309] are imagined. A world of humans with pre-determined characteristics and capabilities could benefit the efficiency, productivity, and manageability of society as a whole. Other governmental fears include, new forms of biological warfare, armies of soldier clones, and the extinction of those found unacceptable to society. Private control over these processes does not erase the fear of abuses. One can imagine menus offering a price list of particularly desirable traits, checklists for couples who would like to opt for specific genetic packages. For the right price, one may have the option to purchase the DNA of a world class athlete, award winning actor, or a beautiful supermodel. As was stated by George Annas, a medical ethicist at Boston University, "Maybe if this were Nazi Germany, we would worry more about the government, but we're in America, where we have the private market. We don't need the government to make the nightmare scenario come true."[310] Fortunately, time is on the side of reason and technology has not progressed to the point where many of the fears expressed will become reality.

Opponents to cloning and other forms of genetic engineering also rely on currently inconclusive information on the long term effects of implanting an adult's DNA into a new being. Fear that the DNA may have mutated to the effect of causing damage to the recipient is one frequently made argument.[311] The recipient may experience rapid aging or suffer more degenerative disease than normal.[312] Other arguments against these procedures are what legal and societal rights are to be afforded to the clone, and a fear that man might insinuate that cloning their own DNA might in turn allow them the opportunity to live forever.

VII. DEBATE: LEGAL ISSUES

With the United States being so heavily involved in the efforts of the Human Genome Project and many other genetic research projects, the legal freedoms guaranteed by the United States Constitution become pivotal issues in the debates over legislation. Legislation enacted throughout the world may prohibit particular areas of research, but if the United States does not agree to accommodate those restrictions, any legislation is virtually meaningless. Traditionally, scientists in the United States assume that, absent a specific and justifiable prohibition, there is

309. *See generally* ALDOUS HUXLEY, BRAVE NEW WORLD (HarperPerennial 1946)(1932).

310. Elmer-Dewitt, *supra* note 9.

311. Cookson, *supra* note 19.

312. *Id.*

freedom to act.[313] This implied freedom, combined with arguments limiting governmental intrusion into fundamental liberties, opens the door to highly complicated debate. With a population consisting of individuals from a multitude of different backgrounds, religions, races, economic status, etc., the difficulty in achieving a consensus opinion on any issue is enormous. Add in personal emotions and moral values, and the debate becomes that much more diluted and difficult to define. Although there are opinions which are not common to all Americans, the collective force of strong objections to the use of cloning on human beings makes a case that it should be against the public policy to conduct this type of research.[314]

In the United States, the amount of governmental intrusion that is permissible on an individual's liberty is dependant upon the classification of the liberty at issue. In the case of ordinary liberties, such as to drive a car, most any reason will be sufficient for government restrictions. For an intrusion upon a fundamental right, those rights mentioned in the Constitution or necessary for a system of ordered liberty, strict scrutiny analysis is performed and a compelling reason is needed for an infringement. Fundamental rights have been defined by the Supreme Court to be those rights so deeply rooted in our culture and history as to be assumed by the public as being beyond casual governmental interference.[315] If a right is not determined to be fundamental, only a rational basis test is utilized before the state may interfere with it.

According to the Supreme Court, Americans have the constitutional right to procreative freedom. The Court found in, *Eisenstadt v. Baird*, that in matters so fundamentally affecting an individual, such as the decision whether to bear or beget a child, it is the right of the person to be free from unwarranted governmental intrusion.[316] Inferences are made based on this holding, that included in the right to have a child is the right to avoid carrying the child to term either through the use of abortion or contraceptives.[317] The dilemma then becomes whether the fundamental right to either give birth or abort a child implies the right to deny life based upon undesirable genetic characteristics or to create life through cloning procedures.

In order to determine whether cloning a human would be protected as a fundamental procreative liberty, the question that must be answered is whether cloning is considered as a form of reproduction or as only

313. *Executive Summary, NBAC Report*, *supra* note 226.

314. *Id.*

315. *Id.*

316. Eisenstadt v. Baird, 405 U.S. 438 (1972).

317. Duffy, *supra* note 308, at 195.

replication. With reference to *Skinner v. Oklahoma*, where according to dicta, coital reproduction is considered a fundamental right, non-compelling state interference with infertility procedures should also be invalidated in the case where the treatment is necessary to allow coitally infertile couples to reproduce.[318] In previous cases discussing procreative liberties, procreation has been assumed to involve interdependent reproductive cooperation between a man and a woman, at least on a biological level.[319] Furthermore, it has been assumed that a vertical transmission of genes, between parent and child, would occur, but through cloning by somatic transfer, genes may be transmitted within a generation.[320] Through the use of embryo splitting, a couple undergoing an infertility procedure may wish to produce more than one child with a particular genome. This may fall within the definition of procreation because the genome that is cloned is from the persons themselves or from an embryo or child that was created from their gametes.[321] Without the use of the person's own genes or gametes, the resulting offspring would be product of replication and not reproduction. Although to some this may be considered to be reproduction, because the process is so deviant from the commonly understood definition, it may not be treated as representing the same fundamental rights.[322] Should the creation of an offspring through cloning technology be regarded as reproduction and protected as a fundamental right, the government must set forth compelling reasons in order validate their infringement. Among the various reasons to prohibit cloning are that through the use of this technology human identity would become predictable and be inconsistent with the maintenance of free will.[323] This is speculated to lead to a weakening of the traditional social constructs found within the family unit and the diminution of the political institutions that focus on restricting coercive manipulation of individuals and fostering individual autonomy.[324] Opponents counter this argument by eliciting the fact that the government has a compelling interest to minimize human suffering and maximize the social good that be achieved through cloning technology. Along with the dilemma that cloning poses to procreative

318. Robertson, *supra* note 94, at 426.

319. *NBAC Report*, *supra* note 225.

320. *Id.*

321. Robertson, *supra* note 94, at 438.

322. *Id.*

323. George P. Smith, II, *Pathways to Immortality in the New Millennium: Human Responsibility, Theological Direction, or Legal Mandate*, 15:2 ST. LOUIS U. PUB. L. REV. 447, 458 (1996).

324. *Id.*

liberty, the pre-birth control over genetic characteristics also comes into the debate. To some, logic dictates that if a woman has the right to avoid birth for any reason, she should be entitled to avoidance for a particular reason.[325] Going a step further, a woman should have the right to reproduce under the circumstances in which she is confident that her child will have particular genetic traits.[326] With the advancements of genetic research, the pre-birth ability to detect genes that are susceptible to disease is improving and is already routinely in use in some situations.[327] Through the continued research in projects, such as the Human Genome Project, the number of diseases that can be detected prior to birth will increase. Interference with one's procreative freedom will occur through the denial of information that may be given to the parents that would effect their decision of whether to reproduce.[328]

If pre-birth selection is determined to be included as a fundamental right, the state must have a compelling reason in order to impede upon that right and a showing of tangible harm to others would probably be necessary. Anything less may not be enough to overcome, at least, the potential pre-birth screening capabilities associated with genetic research. Utilizing an objective test, the materiality of a gene's characteristics to procreative decisions should determine the amount reason necessary to interfere legislatively. Thus, genes which identify serious disease would probably elicit the strict scrutiny test in order to impede, while genes used for nontherapeutic enhancement, intentional diminishment, or cloning would require only a rational basis.[329]

VIII. DEBATE: ETHICAL ISSUES

A. Moral Status of the Embryo

Any discussion or legislation on the topics of cloning and human embryo research must necessarily entail the moral status afforded to the embryo. Countries, and people alike, have opposing views on whether, or under what conditions, research on human embryos may be pursued. There are generally three viewpoints that emerge on the status, or

325. Robertson, *supra* note 94, at 427.

326. *Id.*

327. *Id.* at 429. Medical specialists routinely screen Ashkenazi Jews, African Americans, siblings of those with cystic fibrosis, and other groups to determine their status as carriers of genetic diseases. Doctors also screen over 60% of American pregnancies for neural tube defects.

328. *Id.*

329. *Id.* at 436.

protection, that an embryo is given.[330] Under the first, an embryo is afforded the same protections as any other human being from the moment the egg is fertilized, thus granting the right of an opportunity for life.[331] The second view equates the embryo with any other human tissue, allowing research prior to its viability and with proper consent.[332] The final and majority viewpoint does not equate the status of an embryo with that of a person, but due to the potential for life, more respect is granted than that of ordinary tissue or animal embryos.[333] Proponents of this view allow embryo research to be conducted until the fourteenth day after development began or until the time the embryo can experience brain activity and pain, prior to the appearance of the primitive streak. The majority of countries and international organizations that permit human embryo research to be conducted follow the third viewpoint, with most European nations following the fourteen day limitation.[334]

Constitutional power to regulate these areas of research, along with controlling so-called procreative liberties, varies among the countries of the world, and in most situations the third viewpoint implies a compromise between the first two opposing views. In direct connection with the dilemma that surrounds the abortion debate, individual viewpoints, apart from their government's desired ideology, are deeply entrenched in their own personal beliefs and opposition is not readily accepted. With abortion, some feel that an embryo has the right to life, while others do not afford the embryo such a right. Many believe that it is each individual's choice on whether to partake in an abortion, while others feel that the potential for life creates the obligation to provide the embryo with at least the opportunity for life. Simply put, it is an issue concerning the life or death of the individual embryo, or embryos, involved. What distinguishes the status issue with cloning and genetic technologies from abortion is that the issue is not life or death, but the potential genetic manipulation of future generations and the creation of life when there was none.

B. Individuality and Human Dignity

Critics claim that by cloning humans, children will receive treatment equal to that of a commodity and human dignity and individuality will be diminished. Utilization of splitting techniques to create multiple

330. *See generally* Coleman, *supra* note 41, at 1340.

331. *Id.*

332. *Id.*

333. *Id.*

334. *See* discussion *infra* Council of Europe, International and Domestic Legislation.

clones of a particular embryo will install a feeling of lessened self-worth in the resulting clones because of the association with being artificially manufactured and the knowledge that, not only are you a copy of another, but that there are multiple copies of you.

The lack of harm resulting from the existence of naturally occurring identical twins is often argued as a reason for allowing the use of cloned embryos.[335] Opponents counter this argument by claiming that significant differences between the two make the analogy inappropriate.[336] Initially, while there is a naturally occurring limitation in the number of identical twins born during one birth, usually two or three, with cloning, an infinite amount of embryos can theoretically be produced.[337] Another distinction is that with natural identical twins, birth occurs within a limited time frame, usually moments from each other, but with cloning, birth can occur years apart and with different mothers.[338]

This second distinction brings about an interesting dilemma that has the potential to occur. A child may be faced with a devalued self-worth in light of an identical twin or multiple twins being developed many years subsequent to his or her own birth. This original child may be attached to the notion that he or she is a unique individual and can thus be harmed by some potential future circumstance.[339] This situation also touches on the issue of whether an embryo or a child has the right to individuality and protection against the copying of their genetic composition. While under current conditions it is the rights of the parents which determines what procedures will be accomplished, the existing child is a human being and deserves the same rights as any adult human being, in determining the exploitation of their own unique genetic make-up.

IX. DEBATE: RELIGIOUS ISSUES

Religion vs. Science

The delicate balance that has been created between the advancement of science and the maintenance of fundamental religious beliefs is being threatened by the achievements that have been produced in the area of genetic engineering. Confrontation on issues, such as creation and evolution, have come center stage in the wake of the potential opportunities that are presented as a result of recent advancements. Man,

335. Amer, *supra* note 12, at 1683.

336. *Id.*

337. *Id.*

338. *Id.*

339. *Id.*

through science, is on the threshold of discovering procedures which will allow the manipulation and control over processes that until now, have only been known to nature and *God*. The gap that exists between what can be explained by analytical science and that which is answerable through religious faith is shrinking in the favor of science. But for science to achieve beneficial results for all of humanity, religion must have its place in the debate. The moral and spiritual ideals represented by religion must not be discarded for the sake of scientific progress.

In the new world of genetic engineering, religion's role in society must be re-evaluated in order to help define the most beneficial route to improving life through technology. Fundamental religious teachings on the God-like ability to create life is being tested by potential achievements in genetic manipulation. Opposing views between the many religions further complicates issues on, among other things, the amount of protection given to, or the potential for, human life and permitable areas of genetic research. For example, the Vatican, in condemning attempts to clone humans, warned that because only God can create the spiritual soul, resulting clones will be psychically damaged.[340] With an opposite view, the spiritual guide for the Moslem Hezbollah, Sheikh Mohammed Hussein, claims that because God has allowed science to progress, research into cloning should continue.[341] Lesser debated issues concerning genetic technologies also may encompass opposing religious views. One example is that increased screening for genetic-based diseases will lead to a greater amount of abortions for genetically damaged embryos or fetuses. This situation presents a dilemma for those religions who regard the moment of conception, as when the obligation to protect life begins. The question becomes whether the benefits of providing an improved life to many individuals outweighs the effect of denying life to those who may be genetically handicapped.

The pursuit of scientific achievement must balance its efforts with the moral and spiritual principles expressed in religion. While it is of little doubt that the benefits of cleansing mankind of the burdens of disease and improving overall health is of significant importance and should be continued to be researched, experimentation must proceed within reasonable bounds and protect the cherished notions of birth, dignity, and individuality. Genetic engineering must be used for the greatest societal good and minimize human suffering in order to preserve the integrity of creation and evolution. Memories of the past atrocities that occurred with the Nazis and fear of what can be envisioned should genetic manipulation

340. *Vatican*, *supra* note 287.

341. *Hezbollah*, *supra* note 280.

be used for unsavory purposes, must be combined with moral and spiritual ideals to prevent any misapplication against societal good in these areas of research.

X. DEBATE: THEOLOGICAL ISSUES

Related to the religious issues, theologians have expressed their views on the potential to clone humans and manipulate their genetic constitution. As a fundamental belief, human life is sacred and liberty is a basic right granted to man out of respect for their autonomous and free nature.[342] From there, differing views are formed on how man should handle the knowledge to manipulate creation and control the genetic development of their own species. Some are based on the principle that this science dehumanizes and objectifies the individual by defining the individual's spirit as a mere product of his or her genome.[343] Others take a more consequentialist approach, focusing on whether the results are beneficial given a particular situation.[344] Understanding the importance of the potential benefits that may be achieved, the Roman Catholic Church has even expressed a willingness to condone some circumstances of genetic therapy in conditions of therpeutic necessity.[345] However, any attempt to modify the human genome in a eugenic fashion is strictly against the dignity and identity of man.[346]

Proceeding with caution in the area of genetic engineering, because of a respect for the human spirit, is the basis of thought under the deontological approach.[347] As free and truth seeking individuals, humans can not be the subject of genetic or scientific determination and science must be prohibited from progressing at the expense of the human spirit.[348] If it can be reasonably predicted that no grave harm will be done to the subject and its purpose is to alleviate suffering, genetic therapy may be permissible.[349] Theological beliefs expressed under the consequential theory takes a more fatalistic approach leaning, towards man's inherent nature to manipulate their existence. Justification is realized when the act of manipulation, and the means used to achieve the act, exhibits the

342. Conte, *supra* note 69, at 442.

343. *Id.* at 449.

344. *Id.* at 448.

345. *Id.* at 449.

346. *Id.*

347. *Id.*

348. Conte, *supra* note 69, at 449.

349. *Id.*

greatest societal good for the greatest number of people.[350] Simply put, "[t]he concept of autonomy in bioethics, as well as the individual as a free spirit in theology, is obliterated for the sake of the utility driven social order."[351]

These arguments, as well as those in the religious area, have a basis in the moral and spiritual foundation that society is built upon. Before proceeding with genetic research, scientists must understand what is at stake through the methods utilized and the results that are to be achieved. The moral quality of experimentation is dependant upon the nature of the parties engaging in the procedure, the actual and intended results on the whole human being, and the technological methods employed.

XI. A LOOK TOWARDS THE FUTURE

In the absence of a world wide consensus on the limitations regarding cloning and other genetic technologies, those countries permitting less regulated research will be seeking to cash in on the rapidly expanding biotechnology industry. Some estimates value the market for genetic products and services at over $100 billion, and with the rapid progression of discovery, these estimates are probably conservative.[352] Corporations, and countries alike, are currently in a spirited race to surpass recent advancements, and discover new and profitable techniques in the areas of animal cloning, disease prevention, and gene identification. With the enormous amount of potential profit, pressure to permit continued research, in areas which may be soon prohibited due to overbroad and rushed through legislation, is coming in from scientists and lobbyists in almost every area of genetic research.

A. Government and Corporate Interaction

An enlightened look into the future of partnerships between countries and corporations is occurring in the present time. The first example is centered in Iceland, where with the aid of private United States' investments and the cooperation of the Icelandic public and the government, a genomic company deCode has ventured into twenty-first century research. Utilizing a positional cloning technique, deCode identifies disease-causing genes by looking at the physical characteristics of

350. *Id.* at 448.

351. *Id.*

352. *Looking for Financing, Equity, and Debt: TELECLONE INC.*, FIRST LIST: SEEKING ACQUISITIONS, Nov. 1, 1997.

a disease and working back to its genetic basis.[353] Through this process, researchers have had successful progress in the areas of familial essential tremor and multiple sclerosis.[354] A priority in the project was locating a genetically ideal population base and with the approval of the government and the subject population, Iceland is the perfect fit. With its genetic homogeneity, descended almost exclusively from Norwegian nobles and extensive genealogical records dating back more than two hundred years, the Icelandic people are the ideal model group to research.[355] Add in a top-notch national health care system and a large tissue bank and a virtual Eden is established for the goals of the project.[356]

Claiming to be one of the most technologically advanced companies in the world, deCode reports to be able to map up to twelve complex diseases per year through sequencing operations which are able to generate 300,000 genotypes per month.[357] Subject to governmental approval, deCode plans to establish a database, called GGPR, containing the genotypes, genealogy, and phenotypes of the Icelandic population.[358] This will allow the identification of diseases which occur in specific families and determine its genetic basis through generational inheritance of the disease.

An opposite situation has occurred in Manilla, where in an effort to combat *bio-piracy*, the government has attempted to prevent foreign corporations from patenting genetic material found in their territory. As of September 1, 1997, the government has voided any agreement with multinationals granting the right to isolate and patent genetic material from flora and fauna located in the Philippines.[359] Any bio-prospecting must be accomplished with a government license and the consent of the community involved.[360] Similar concerns have been raised in Indonesia and other countries, but lack of adequate enforcement allows illegal exporting to be done.[361]

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353. *deCode Genetics puts Iceland on the Map*, MARKETLETTER, OCT. 13, 1997.

354. *Id.*

355. *Id.*

356. *Id.*

357. *Id.*

358. *Id.*

359. Choong Tet Sieu & Keith Loveard, *Biotech: Magic Genes*, ASIAWEEK, Sept. 5, 1997.

360. *Id.*

361. *Id.*

B. Recent Progress

To illustrate how quick progress is being achieved, since the time I began research on this topic, the technology used to create Dolly the sheep has already been reported to be improved upon. According to officials at ABS Global Inc., located in Wisconsin, three genetically identical calves have been produced from a single fetal calf tissue and ten cows are currently impregnated with clones from a single adult bull cell.[362] Rather than starving the cells of growth factors and nutrients like researchers in Scotland, ABS advanced the process by creating stem cells by using a special formula of growth hormones to modify specialized cells.[363] Through the successful use of this new procedure, ABS claims that safety concerns are minimized, and cloning a human, should that route be taken, would become a much technically safer process.[364]

Recent corporate influence in cloning technology has also begun to produce therapeutic benefits for man through efforts in animal cloning, Two companies, Genzyme Transgenics Corporation and Advanced Cell Technology Inc. have joined efforts to clone transgenic cattle which produce milk laced with human therapeutic proteins.[365] Advanced Cell utilizes a proprietary method of cloning, in which they introduce a gene into fetal fibroblast cells in culture and then transfer the nuclei of those cells into enucleated egg cells.[366] The resulting embryos, all female, are implanted into surrogate mothers, thus creating a herd in one generation.[367] Genzyme Transgenics, on the other hand, has previously produced transgenic goats capable of producing Antithrombin III, a human protein, in their milk.[368] Together, they aim to produce cattle containing human serum albumin, a market currently valued at $1.5 billion.[369] Human serum albumin is used to regulate the balance of protein and fluids in the blood of patients who are undergoing major surgery or suffering from burns, shock, or malnutrition.[370] This is only one example of a recent advancement in

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362. *Wisconsin Researchers Clone Three Genetically Identical Calves*, TRANSPLANT NEWS, Aug. 31, 1997.

363. *Id.*

364. *Id.*

365. Lisa Seachrist, *Genzyme Transgenics, Advanced Cell Clone Cows to Produce Human Albumin*, 8 BIOWORLD TODAY 196, Oct. 9, 1997.

366. *Id.*

367. *Id.*

368. *Id.*

369. *Id.*

370. *Id.*

genetic engineering and new discoveries are being reported in newspapers and trade magazines everyday.

C. *The Future?*

If the technologies associated with cloning are allowed to progress, what will the future of child birth look like? Will corporations begin soliciting customers by offering menus of genetic characteristics for one to choose from? How about those opportunistic businessmen who compile licensing agreements from world-class athletes, famous actors, and beautiful supermodels, to sell cloned DNA to the highest bidders? The possibilities and the horrors seem endless when considering the effect the free market will have on profiting from these potential procedures.

One such entrepreneur took the initiative and began a business called Geneti-Pet, where pet owners can one day receive a clone of their beloved deceased pet. For a minimal fee of only $75, a blood retrieving kit is sent to you, for a veterinarian to take a blood sample.[371] With an additional cost of $200 per year, your pet's genetic composition is cryogenically frozen until technology becomes available to replicate the DNA.[372]

For those seeking to invest their money into the potential of cloning, opportunities exist to invest in genetic research corporations. Besides previously established companies, which are privately financed or located on the many stock markets, companies are now soliciting investors in trade magazines and on the Internet. One such company is Teleclone Inc., who hopes to generate enough capital to maintain genetic laboratories to clone genes and provide genetic services and products.[373] Another potential investment is in the Raelian Movement, a religious organization claiming that life on earth was scientifically created in laboratories.[374] The organization is seeking to establish a laboratory in a country allowing cloning to be achieved and to sponsor private American laboratories that no longer receive funding due to the federal ban. Looking to charge upwards of $200,000 to clone an embryo, the Raelians will also provide an insurance service to provide storage of a child's DNA in order to clone a prematurely deceased child.[375] For a final look at a potential future

371. Sean Griffin, *A Bowser in a Bottle*, THE NEWS TRIB. (TACOMA, WA.), Feb. 1, 1994, at A1.

372. *Id.*

373. *Looking for Financing*, *supra* note 352.

374. *Rael Creates the First Human Cloning Company* (visited Sept. 25, 1997) <http://rael.org/English/pressreleases/clone.html>.

375. *Id.*

situation, Dream Tech International, an Internet site, offers a sampling of hypothetical order forms and company benefits that encompass a futuristic human cloning company.[376]

XII. CONCLUSION

As the world is on the threshold of entering a new millennium, the ability to manipulate the existence of humanity in a way never before experienced is presented before us. Potential advancements in genetic engineering technology offers man the power to create and control the future development of life on earth and the ability to alter nature in a truly God-like manner. The awesome responsibilities and implications derived from these advancements must not be taken lightly and the principles of human dignity and individuality should not be forsaken. The ramifications implicit in modifying the genetic composition of man will affect all individuals, no matter their location or status in society. The positive benefits to the overall health and improvement of the human species must be balanced by the effects research will have on potential life and the loss of individual freedoms which may ensue. In simple terms, the path in which science chooses to progress will have the effect of altering not only present society, but all future generations of offspring.

An international consensus is an absolute in issues of this magnitude. With the potential for enormous profits, anything less than a world wide agreement, in either direction, is necessary to protect against procreative tourism and corporate influence in these areas. While that notion is admirable, in today's society economy-driven legislation and corporate lobbying are major influences in dictating the course of regulations. In this matter, the decision must be one which is beneficial to all of man, and not to those who stand to profit off of this technology.

Positive arguments in favor of conducting research in these areas of science are very convincing and the potential medical and social benefits to society are inspiring. The prevention or extinction of serious disease and the reduction of overall human suffering are admirable goals and should be pursued with the utmost effort. Proponents of cloning research also point to other areas of research including psychology, sociology, and anthropology, that support the view that the environment which one develops from and the experiences one encounters, along with genetic composition, determine the actual identity of an individual. Therefore, attempts at cloning would not be detrimental to the principles of human

376. *Dream Tech International* (visited Sept. 25, 1997) <http://www.d-b.net/dti/about.html>.

dignity and individuality and should thus be research in order to achieve the potential benefits to society, as a whole.

Although the proponents have convincing views, so do the critics of these procedures. With the lack of any conclusive information on the implications that cloning and genetic manipulation would cause on humanity, opponents are reluctant to accept any research that may be abused with such disastrous consequences. The risks involved, not only to personal freedoms, but to the subjects involved in any experimentation, are not justified by the possibilities that have the potential to be achieved. Basic religious and personal beliefs are at stake, and many people are not willing to reject long-standing ideals for the benefit of science.

Favorable public reaction to these new biotechnologies is consequential to their gaining approval to be researched and so far the response has not been positive. According to a Time/CNN poll conducted in 1993, three out of four Americans found the idea of cloning humans to be deeply troubling and forty percent would put a temporary halt on any research.[377] Regarding moral and religious issues, sixty-three percent of those polled believed cloning was against God's will and fifty-eight percent thought that cloning was morally wrong.[378] Furthermore, forty-six percent of Americans were favorable towards imposing criminal sanctions for attempting to clone a human being.[379]

At the outset of researching these issues it was my opinion that any attempt at cloning or genetically manipulating an individual was wrong, as it was against my own personal beliefs and moral foundation. During my research, my opinion varied on an almost daily basis, depending on whose views I was reading and the benefits and risks that were involved. Now at the conclusion of writing this paper, confusion exists and although I still believe it is wrong, I am hesitant in discounting all the potential benefits to society that may be achieved through continued research. In my life, I have not experienced the untimely death of a young child or have child who is seriously affected by a genetic disease. I do not understand the grief that a parent must feel in the loss of a child, or the mindset of those who would want to replace a deceased child with a cloned copy. As a single man, without any attempts at conceiving a child, I also do not understand the pain of infertility for myself, or that of a spouse.

The reason I say these things is because I do understand that these issues must be debated by all of mankind and views from those who have experienced many of the issues involved must be heard, thus allowing

377. Elmer-Dewitt, *supra* note 9.

378. *Id.*

379. *Id.*

everyone to realize the true implications that are involved. As a member of the human race, my opinion, as well as others must be considered by governments in deciding what direction to proceed in and what will be most beneficial to man.

At the present time and with so much still to learn, any attempt to clone a human being or modify the genetic composition of an individual, which would have the effect of alter future generations, should be prohibited. Until such time that the public is favorable towards these procedures and information is offered which is convincing in eliminating the fear of abuses, science must not proceed in this direction.