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Regulation of Human Cloning: Implication for Biotechnological Advancement

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Note

REGULATION OF HUMAN CLONING: IMPLICATIONS FOR BIOTECHNOLOGICAL ADVANCEMENT

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I. INTRODUCTION

The birth in Scotland in 1997 of an apparently healthy lamb named Dolly represents to scientists and many others another milestone in the ability of the human race to control its destiny. However, because Dolly was cloned from the cells of an adult ewe, her birth has also engendered a great deal of concern. Now, the ability of science to clone humans seems imminent. As a result, governments around the world are grappling with the ethical implications of what was only recently thought an impossibility. However, widespread governmental opposition to the prospect of human cloning in Europe and the United States may adversely affect the biotechnological industry's efforts to further develop the science of cloning in general and consequently hinder beneficial applications of this technology.

This Article will examine the societal effects of cloning and the French, British, and American responses to the recent scientific advances in cloning technology. Part II will explain the scientific discoveries that have made possible various methods of mammalian asexual reproduction. Part III will discuss possible applications of cloning technology. Part IV will examine moral and ethical objections to the use of cloning technology to produce humans and the countervailing considerations in support of such cloning. Part V will analyze governmental reactions in France, the United Kingdom, and the United States to the prospect of human cloning.

II. SCIENTIFIC DISCOVERIES IN MAMMALIAN ASEXUAL REPRODUCTION

The word "clone" can legitimately be used to describe any human intervention that results in a precise genetic copy of living matter, whether the subject of reproduction is a specific molecule, cell, plant, animal, or human

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being.[1] All organisms start out as a collection of totipotent cells, cells having the full genetic potential to develop into a whole organism.[2] While plants and many simple invertebrate animal species retain the ability to regenerate a whole organism from a small piece, invertebrates lose this ability to regenerate once their cells differentiate.[3] Cell differentiation, which occurs after only a few phases of cell division, permits the transformation of totipotent cells into the specialized cells that will develop into the various complex tissues of the organism.[4]

A. Blastomere Separation

In nature, monozygotic (identical) twins result from the cleavage of totipotent cells following cell division. Although such twins are a rare phenomenon, spontaneously occurring only in four out of every one thousand births, scientists have been able to induce cleavage of totipotent cells in sheep and cows for nearly twenty years.[5] This technique, called blastomere separation, was used in 1993 to induce the identical twinning of non-viable human embryos.[6] In that experiment, scientists successfully formed forty-eight new embryos from the still-totipotent cells of seventeen embryos. Both the original seventeen embryos and the resulting embryos were abnormal, however, and were not capable of implantation and gestation.[7] Only after this research had been presented to the scientific community did the technique become known as a form of cloning.[8]

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1. *See* NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 13 (1997) [hereinafter NBAC REPORT].

2. *See id.* at 14.

3. *See id.*

4. *See* Jacques Cohen & Giles Tomkin, *The Science, Fiction, and Reality of Embryo Cloning*, 4 KENNEDY INST. ETHICS J. 193, 195 (1994).

5. *See* COMITÉ CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (Fr.) [NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES], REP. NO. 54: REPLY TO THE PRESIDENT OF THE FRENCH REPUBLIC ON THE SUBJECT OF REPRODUCTIVE CLONING: SCIENTIFIC AND TECHNICAL ASPECTS 7, 12 (Apr. 22, 1997) <http://www.ccne-ethique.org/ccne_uk/avis/a_054.htm> [hereinafter COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS].

6. *See* Jerry L. Hall et al., Experimental Cloning of Human Polyploid Embryos Using an Artificial Zona Pellucida (Oct. 13, 1993) (unpublished paper, presented at the Meeting of the American Fertility Society conjointly with the Canadian Fertility and Andrology Society), abstract *in* 57 FERTILITY & STERILITY S1 (Program Supp. 1993).

7. *See* National Advisory Board on Ethics in Reproduction (NABER), *Report on Human Cloning Through Embryo Splitting: An Amber Light*, 4 KENNEDY INST. ETHICS J. 251, 251 (1994) [hereinafter NABER].

8. *See* Cohen & Tomkin, *supra* note 4, at 196.

With blastomere separation, the existence of at least one embryo is necessary, therefore requiring an initial union of the male and female reproductive gametes.[9] By isolating individual cells of a two- to eight-cell embryo soon after fertilization *in vitro,* scientists are able to grow each cell or cluster of cells into a maximum of four separate, genetically identical embryos.[10] These embryos may then be transferred to the womb of a gestational mother and carried to term.[11] This procedure, which has resulted in an increased pregnancy rate for cattle,[12] has apparently not yet been used clinically to assist in achieving a live human birth.[13]

The nature of cellular division precludes blastomere separation from producing a large number of identical children. Embryonic cells only retain their totipotency through two or three cell divisions and apparently keep a running tally of the number of divisions through which they have progressed.[14] Blastomere separation does not set the clock back for any of the cells separated, making further attempts to use the technique futile.[15] Because of its inherent numerical limitations, blastomere separation does not differ significantly from the more prevalent *in vitro* fertilization (IVF) procedures. While the former necessarily produces identical twins, the latter have been regarded as producing the equivalent of spontaneously occurring fraternal twins.[16]

B. Nuclear Transplantation

As with blastomere separation, embryos may also be multiplied through the process of nuclear transplantation. In this technique, the genetic material from a recipient egg is removed, leaving only the egg cytoplasm and mitochondrial DNA.[17] Once the egg has been enucleated, the cell nucleus from an embryo, including the genetic material, may be introduced into it. A pulse of electric current is then used to activate the transformation of this egg into an embryo, and the DNA housed in the egg's new nucleus directs its development into a

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9. *See* Ruth Macklin, *Splitting Embryos on the Slippery Slope: Ethics and Public Policy,* 4 KENNEDY INST. ETHICS J. 209, 212 (1994).

10. *See* Cohen & Tomkin, *supra* note 4, at 199-200.

11. *See id.* at 199.

12. *See id.* at 196-97

13. *See* Macklin, *supra* note 9, at 220-21.

14. *See* Cohen & Tomkin, *supra* note 4, at 199-200.

15. *See id.* at 200. Even assuming it is possible to clone fifteen healthy embryos using blastomere separation, the number of live children currently born as a result of embryo transfer following IVF should alleviate any fears that a large proportion of the cloned embryos would be born. For example, the twenty percent birth rate claimed by the most advanced fertility clinics should lead to the live birth of only three of fifteen embryos separately implanted and gestated. *See id.*

16. *See* Macklin, *supra* note 9, at 222-23.

17. *See* NBAC REPORT, *supra* note 1, at 15, 20, 21.

genetic copy of the original embryo.[18] Large numbers of genetically identical embryos could be produced by using nuclear transplantation techniques on multiple generations of cloned embryos, all tracing their lineage back to a single embryo parent.[19] Although scientists have not yet used this process with humans, scientists have routinely cloned sheep and cows using nuclear transfer over the past ten years.[20]

Until recently, scientists believed that the successful cloning of a viable human would require, as a starting point, the existence of a human embryo.[21] For invertebrates, the totipotency of embryonic cells, as described above, was believed to be the key to the development of an entirely new organism.[22] The live birth of Dolly, an apparently normal lamb cloned from the mammary cells of an adult ewe, demonstrates that cell differentiation and specialization are reversible, given the proper environment. It also demonstrates another possible technique for asexual reproduction—through nuclear transfer from an adult somatic cell, the genetic material from only one parent may be used to asexually create an embryo, resulting in a delayed genetic twin of the adult.[23]

However, the success rate of the somatic cell nuclear transfer process that led to Dolly shows that this technology is still far from being a realistic reproductive option. Out of 277 attempts using nuclear transfer, only Dolly was born.[24] Nevertheless, despite the inefficiency of nuclear transfer of differentiated cells, the ready availability of female eggs and of male or female cells in the human population makes the cloning of an adult human through this technique a realistic scientific possibility.

The creation of a delayed genetic twin, however, does not require nuclear transfer of an adult somatic cell. Following either blastomere separation or the nuclear transfer of genetic material from an embryonic cell, cloned embryos could be cryogenically preserved. Cryogenic preservation is a freezing process currently used to store embryos not immediately implanted following IVF,

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18. *See id.* at 15, 20.

19. *See* Cohen & Tomkin, *supra* note 4, at 198.

20. *See* NBAC REPORT, *supra* note 1, at 1, 20. The birth weight of the resulting calves appears to be higher than normal, but this increase has also been reported following the application of IVF procedures in cattle. *See* Cohen & Tomkin, *supra* note 4, at 198. Further development of the cloned calves has been normal. *See id.* at 198, 200.

21. *See Biotechnology and the Ethics of Cloning: How Far Should We Go? Hearing Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. 11 (1997) (statement of Harold Varmus, Director, National Institutes of Health) [hereinafter *Ethics of Cloning*].

22. *See* NBAC REPORT, *supra* note 1, at 15-16.

23. *See id.* at 1, 3, 16.

24. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 8.

permitting multiple implantation attempts.[25] Freezing and thawing may, however, lessen an embryo's ability to successfully implant.[26] Moreover, embryos not subsequently implanted must be either discarded or allowed to disintegrate over time.[27]

III. POSSIBLE APPLICATIONS OF CLONING TECHNOLOGY

A. Applications with Domestic Animals

Numerous biotechnological applications of cloning technology to the domestic animal population are possible. Cloning technology could permit scientists to generate groups of genetically identical animals for research purposes, reducing the number of total animals needed for comparative veterinary treatments, herd management studies, and studies of animal association and feeding behaviors.[28] Similarly, by producing groups of cloned animals with gene alterations targeted to appropriate regions of the chromosome, it would be possible to efficiently create animal models for human genetic diseases in species more complex than mice and rats and to validate protocols for new medical treatments using a smaller number of better defined animals.[29] However, because each subject in the research sample would need to be reproduced by nuclear transfer, the generation of a large enough number of animals to be useful as an experimental group may be prohibitively expensive in many species.[30] Nevertheless, this objective motivated the successful cloning of a group of rhesus macaque monkeys in Oregon in 1997,[31] suggesting that the benefits to researchers of eliminating the genetic variable from their research subjects may outweigh any difficulty in obtaining sufficiently large subject groups.

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25. *See* NABER, *supra* note 7, at 268; COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 10-13.

26. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 13.

27. *See* NABER, *supra* note 7, at 268.

28. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 7.

29. *See id.* at 8. Genetically modified farm animals would provide a better model for the study of diseases such as cystic fibrosis, a human pathology which manifests itself differently in rodents. *See Scientific Discoveries in Cloning: Challenges for Public Policy: Hearing Before the Subcomm. on Pub. Health and Safety of the Senate Comm. on Labor and Human Resources*, 105th Cong. 16 (1997) (statement of Harold Varmus, Director, National Institutes of Health) [hereinafter *Scientific Discoveries*].

30. *See* NBAC REPORT, *supra* note 1, at 25.

31. *See Ethics of Cloning*, *supra* note 21, at 19-20 (statement of M. Susan Smith, Director, Oregon Regional Primate Research Center).

Another application of cloning technology to domestic animals will be the ability to rapidly propagate desirable animal stocks. The progress that animal breeders presently achieve through conventional genetic selection takes many years to reach the average commercial farmer. A limited number of cloned animals could substantially speed up this process, enabling livestock breeders to respond more quickly to changes in customer demand and permitting all farmers to produce the highest quality animals.[32] By increasing the effective reproductive output of "elite" male and female animals, animal breeders could rapidly spread commercially desirable traits.[33] Among the benefits to be realized in livestock are decreased E. coli and salmonella susceptibility, increased lean mass, and increased milk production.[34] Such improvements will be increasingly necessary to feed a rising world population.[35] Cloning in large numbers, however, could increase the risk of depleting genetic diversity, placing generations of animals at the mercy of uncontrollable, and unknowable, environmental threats.[36] Nevertheless, cloning technology may resolve this problem by ensuring a pool of genetically diverse animals for future livestock maintenance.[37]

B. Applications with Endangered Animal Species

Likewise, among poorly reproducing and endangered species, cloning may actually increase genetic diversity in the long term by increasing the total population of a species.[38] The lack of success attributed to present methods of wild animal conservation frustrates scientists and environmentalists alike, who estimate that these efforts will not prevent the extinction of ten percent of the earth's species before the turn of the century.[39] Nuclear transfer cloning technology could be used to preserve and even rescue animal species on the

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32. *See Scientific Discoveries*, *supra* note 29, at 21 (statement of Ian Wilmut, Embryologist, Roslin Institute, Edinburgh, Scotland).

33. *See* NBAC REPORT, *supra* note 1, at 25.

34. *See Scientific Discoveries*, *supra* note 29, at 69-70 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

35. *See Agricultural Research: The Most Vital Investment for People and the Environment: Hearing on Agricultural Research Before the Senate Agric. Comm.*, 105th Cong. 1, 6 (1997) (statement of Dennis T. Avery, Director of Global Food Issues, Hudson Institute). A full 90% of the 8.5 to 9 billion people projected to inhabit the world by 2035 are expected to consume protein-rich, non-vegetarian diets, requiring a doubling or tripling of the current production in milk and meat products. Increases in demand are already beginning to occur in Asian countries. *Id.*

36. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 9.

37. *See* NBAC REPORT, *supra* note 1, at 25.

38. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 8.

39. *See* H.R. REP. NO. 102-259, pt. 1, at 10 (1991). If extinction continues at present rates, more than 25% of all living species will become extinct within the next couple of decades. *See id.*

brink of extinction, reconstructing particular species' populations.[40] Because exploitation of genetic variability underlies most biotechnological advances, cloning could be used to ensure a wide genetic base within all species, permitting future agricultural and medical breakthroughs.[41] Although society depends upon biological resources to provide the raw materials for food, most pharmaceuticals, clothing, and shelter, fewer than five percent of the species on earth have been tested for either food or pharmaceutical potential. Loss of species and genetic diversity will irreversibly diminish this pool of resources.[42]

C. Application with Transgenic Livestock

Perhaps the most exciting and beneficial application of cloning technology involves transgenic livestock.[43] Transgenic animals are genetically altered animals that are presently created by directly injecting genes from other species into fertilized eggs.[44] Animals that express the desired genes offer remarkable pharmaceutical and medical benefits to humankind. The milk of livestock animals can be modified to contain large amounts of pharmaceutically important proteins. For example, human drugs such as insulin and factor VIII can be produced more cost-effectively through transgenic animals than they are currently produced.[45] Transgenic sheep and cattle already produce large quantities of proteins in their milk to treat human diseases such as emphysema and cystic fibrosis.[46] In addition, the use of transgenic milk to produce products that are currently derived from sources such as pooled human plasma provides a significantly safer alternative to present production methods, which necessarily involve some risk of transmitting infectious human diseases.[47] Because transgenic technology enables the high volume, highly purified, and low cost production of complex protein therapeutics that either cannot presently be produced or are produced on a limited and inefficient basis using existing technologies,[48] the cloning of transgenic animals may be particularly valuable to countries whose populations enjoy only minimal medical resources.

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40. *See* Charles Arthur, *Cloning Could Be Lifeline for Threatened Species*, INDEP. (London), Sept. 11, 1997, at 6.

41. *See* H.R. REP. NO. 102-259, pt. 1, at 18.

42. *See* H.R. REP. NO. 102-259, pt. 1, at 16-17.

43. *See Scientific Discoveries*, *supra* note 29, at 1 (statement of James A. Geraghty, CEO, Genzyme Transgenics Corp.).

44. *See* NBAC REPORT, *supra* note 1, at 26.

45. *See id.*

46. *See Scientific Discoveries*, *supra* note 29, at 21 (statement of Ian Wilmut, Embryologist, Roslin Institute, Edinburgh, Scotland). Transgenic livestock have also produced anti-clotting drugs for heart attack and stroke treatment, clotting drugs for bleeding deficiency treatment, anti-cancer drugs, and nutritional supplements. *See id.* at 71 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

47. *See id.* at 2 (statement of James A. Geraghty, CEO, Genzyme Transgenics Corp.).

48. *See id.* at 71 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

Transgenic animals may soon offer yet another benefit to humans: they may become a principal source of organs for the many individuals desperately needing organ transplants. Transplantation has been a phenomenal success for thousands of people with life-threatening conditions, and this success has caused the demand for organs worldwide to grow at a rate of fifteen percent per year.[49] The treatment of patients with severe and debilitating diseases through organ transplantation significantly reduces health care costs, saves lives, improves recipients' quality of life, and permits increased participation in the work force.[50] Unfortunately, the supply of donor organs has not kept up with the growing need, and demand is expected to increase even more as improved techniques and anti-rejection medications make treatment possible for many individuals who are presently considered too vulnerable for organ transplantation.[51]

Transplantation of animal organs into humans could solve the donor organ shortage, but only if science is able to overcome the hurdle posed by the recipient body's immunological reaction, known as hyperacute rejection.[52] Because anti-rejection medicines cannot presently overcome this problem, it is avoided in human-to-human organ transplants only by carefully matching donor organs with their recipients.[53] If animal organs are transplanted into humans, transgenic pigs are the most likely organ donors. Pig organs, both in infancy and adulthood, approximate the development of human organs in size and physiology, and pigs' short gestation times, large litters, and disease resistance could generate a large number of lifesaving organs quickly.[54] While the human body's rejection of pig organs can already be partially overcome by the expression of certain regulatory proteins in transgenic pigs, further transgenic manipulation may be able to minimize or eliminate problems of organ rejection,[55] providing a regulated, controlled source of donor organs for human transplantation.[56]

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49. *See id.* at 62 (statement of John Wallwork, Director of Transplantation Servs., Papworth Hospital, Cambridge, England). The current need for organ transplantation in the U.S. has been conservatively estimated to exceed 120,000 solid organs per year. *See id.* at 70 (statement of Leonard Bell, CEO, Alexion Pharmceuticals, Inc.).

50. *See id.* at 70.

51. *See id.* at 62 (statement of John Wallwork, Director of Transplantation Servs., Papworth Hopital, Cambridge, England). Nine people die every day in the U.S. because of the inability to obtain a suitable organ for transplantation. *See id.*

52. *See id.* at 63. Rejection occurs when the recipient body's immune system attacks the newly transplanted organ, killing it within a few minutes.

53. *See id.* at 71 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

54. *See id.* at 70. *See also id.* at 63 (statement of John Wallwork, Director of Transplantation Servs., Papworth Hospital, Cambridge, England) (adding that pigs breed relatively quickly).

55. *See* NBAC REPORT, *supra* note 1, at 26.

56. *See Scientific Discoveries, supra* note 29, at 71 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

Creation of transgenic animals by injecting genes into fertilized eggs neither ensures that the injected eggs will develop into transgenic animals nor that the transgenic animals will express the added gene in the desired manner.[57] Nuclear transfer would allow more efficient generation of transgenic animals than is currently possible by permitting scientists to use, as the source of donor nuclei for cloning, only those cells already known to express the added gene in the desired manner.[58] Moreover, successful use of cloning technology in livestock would give scientists a new found ability to remove genes, which could make possible important improvements and additional products presently unavailable through current methods of transgenic production.[59]

D. Applications with Human Beings

Applications of cloning, of course, extend beyond the use of domestic animals. The next logical step in applying cloning technology involves basic research on cell differentiation.[60] Every human cell has approximately 80,000 genes, each of which is turned on or off during the course of forming the 200 or so different types of cells in the human body.[61] If scientists can gain a better understanding of the ways in which cells grow, divide, and become specialized, it may become possible to direct cell differentiation along a specific path to produce specific tissues for therapeutic transplantation, without concern for immunological rejection.[62] Guiding cell differentiation in this way may facilitate the development of cell grafts to aid the recovery of burn victims and to allow transplantation of hematopoietic stem cells for those suffering from leukemia and other diseases of the blood, neuronal cells for those suffering from Parkinson's disease and Huntington's chorea, and endocrine pancreatic cells for those suffering from diabetes.[63] It may also make it possible to repair severed spinal cords,[64] cure or reverse malignant tumors,[65] provide much needed bone

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57. *See* NBAC REPORT, *supra* note 1, at 26. Currently, less than one percent of injected eggs will produce a transgenic animal in which the added gene has become incorporated into the animal's DNA, and even in these cases the transgene may not be very efficiently translated into the desired protein. *See Scientific Discoveries supra* note 29, at 21 (statement of Ian Wilmut, Embryologist, Roslin Institute, Edinburgh, Scotland).

58. *See* NBAC REPORT, *supra* note 1, at 26.

59. *See Scientific Discoveries, supra* note 29, at 69 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

60. *See* NBAC REPORT, *supra* note 1, at 29-30.

61. *See Scientific Discoveries, supra* note 29, at 16 (statement of Harold Varmus, Director, National Institutes of Health).

62. *See* NBAC REPORT, *supra* note 1, at 30.

63. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 14.

64. *See* American Ass'n for the Advancement of Science, Ctr. for Science & Tech. in Congress, *Cloning Raises Tough Policy Questions for Congress* ¶4 (Apr. 1997) <http://www.aaas.org/ SPP/DSPP/CSTC/bulletin/articles/4-97/cloning.htm>.

65. *See* Cohen & Tomkin, *supra* note 4, at 195.

marrow for chemotherapy patients,[66] and eradicate arterial disorders and heart disease.[67]

At the molecular and cellular levels, scientists have been using cloning technology for several decades. The cloning of DNA at the molecular level and of cell lines at the cellular level provides researchers with greater quantities of identical genes or cells for study while eliminating undesirable genetic variability. Cloning of this type has led to the production of insulin to treat diabetes, tissue plasminogen activator (TPA) to dissolve clots after a heart attack, and erythroprotein (EPO) to treat anemia secondary to kidney disease.[68] Molecular research has also generated lifesaving treatments for cancer, strokes, kidney failures, liver infections, and multiple sclerosis and has produced anti-rejection medicines to protect transplanted organs.[69] Because these applications of cloning do not involve the germ cells required for human reproduction, the cloned cells cannot develop into a human embryo.[70]

Beyond molecules and cells, cloning technology has made possible the creation of viable human embryos that apparently may be implanted in a womb and carried to term.[71] Some applications of cloning technology, discussed below, could be used to create viable embryos not intended for implantation. Yet any research performed on such embryos could lead to their destruction.[72] Guidelines in the United States and abroad do not generally restrict embryo research on normal embryos until approximately fourteen days after fertilization, after which time research is to cease and the embryos are to be discarded. This period mirrors the time at which implantation normally occurs and the primitive streak, believed to characterize a single developmental entity, first appears.[73] Because genetically identical subjects are quite valuable scientifically and the scientific community generally accepts non-therapeutic research on embryos before the development of the primitive streak, those scientists who find research on human embryos invaluable to the study of early embryonic development and cell differentiation are likely to use cloning technology to accomplish their scientific objectives.[74]

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66. *See Scientific Discoveries*, *supra* note 29, at 16 (statement of Harold Varmus, Director, National Institutes of Health).

67. *See* Cohen & Tomkin, *supra* note 4, at 195.

68. *See* NBAC REPORT, *supra* note 1, at 14.

69. *See Scientific Discoveries*, *supra* note 29, at 68 (statement of Leonard Bell, CEO, Alexion Pharmaceuticals, Inc.).

70. *See* NBAC REPORT, *supra* note 1, at 14.

71. *See id.* at 64.

72. *See* NABER, *supra* note 7, at 262.

73. *See id.* at 263.

74. *See id.* at 273.

In addition to researchers, clinicians may envision many opportunities to use cloning technology to advance human reproductive goals, especially methods of cloning that may improve the chances of initiating pregnancy in individuals who produce only a limited number of embryos for transfer and implantation through IVF.[75] Only ten percent of the embryos obtained through IVF are successfully implanted.[76] Because, on average, only two or three embryos at a time are transferred, on average, the success rate (births per attempt) is only fifteen percent.[77] Given the low rates of pregnancy and live birth attributed to IVF, reproductive specialists may be particularly interested in blastomere separation. This technique already works well in cattle, and it will likely work with the same efficacy in human reproduction.[78]

Patients who are able to generate only a single embryo for transfer using IVF are the primary candidates to receive duplicated embryos; however, they may nevertheless find only marginal hope in blastomere separation. Some failures during the procedure itself would reduce the number of embryos available to transfer.[79] In such cases, the embryonic nuclear transfer technique would be more likely than blastomere separation to produce sufficient numbers of embryos for implantation.[80] Because nuclear transfer is much more technically difficult than blastomere separation, involving the direct manipulation of genetic material,[81] nuclear transfer is likely to be a more expensive method of reproducing the relatively small number of embryos desired for implantation.

Moreover, it is presently unclear whether genetic heterogeneity plays a role in the successful implantation of embryos. Some scientists speculate that embryos with genetically superior composition implant more frequently than others and that patients requiring IVF produce embryos with a genetically

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75. *See id.* at 267. More than 5,000,000 American couples are presently affected by infertility. *See Banning Federal Funds for Human Cloning Research: The Prohibition of Federal Government Funding of Human Cloning Research: Hearings on H.R. 922 Before the Subcomm. on Tech. of the House Comm. on Science,* July 22, 1997, *available in* LEXIS, Legis. Library, Cngtst File [hereinafter *Banning Federal Funds*] (statement of Arthur F. Haney, President-elect, Am. Soc'y for Reprod. Med.).

76. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 13.

77. *See id.*

78. *See* Cohen & Tomkin, *supra* note 4, at 198.

79. *See id.* at 199. Reducing the size of an embryo by division may destroy or damage it, diminishing its potential for successful implantation in the womb. *See* NABER, *supra* note 7, at 255.

80. *Cf.* Cohen & Tomkin, *supra* note 4, at 198 (noting that unlike blastomere separation, nuclear transfer of a cell from a cloned embryo could be repeated on each successive embryo so created).

81. *See* NABER, *supra* note 7, at 252.

inferior composition.[82] If so, although blastomere separation or nuclear transfer would provide greater numbers of embryos for implantation, neither technique would result in an increase in implantation among embryos with an identical but genetically inferior composition.[83] Therefore, in the case of an embryo that is not likely to implant, using these methods of cloning would only multiply the failure that the original embryo's genetic makeup made inevitable.[84]

If genetic homogeneity does not adversely affect the ability of embryos to successfully implant, both cloning techniques have the potential to lower the costs and the risks associated with the use of IVF in a single egg retrieval procedure. By providing greater numbers of embryos for implantation from a single procedure, cloning could reduce the number of times that egg retrieval procedures would need to be carried out on a patient.[85] Because IVF presently requires the full-time attention of one health-care worker in order to complete the average ten IVF procedures in a single year, any simplification of the medical and laboratory procedures would increase the efficiency of the health care system and lower the cost of each IVF procedure.[86]

In addition, both cloning techniques could reduce the risks posed to IVF patients. If the standard number of eggs needed to arrive at successful implantation decreased dramatically, the natural menstrual cycle would produce sufficient eggs for the IVF procedure and neither repeated administration of anesthesia nor fertility drugs would be a necessary risk.[87] Alternatively, by combining either the blastomere separation or nuclear transfer technique with cryogenic preservation, cloning could permit the creation of additional embryos not intended for immediate transfer to the womb.[88] Once preserved, these embryos could be stored and later thawed for a subsequent round of IVF, thus obviating the need for an additional retrieval procedure.[89]

For some couples, infertility problems stem from the absence of reproductive gametes.[90] When the prospective parents are infertile or the prospective father has non-functional sperm, cloning one member of the couple through nuclear transfer would provide a means of producing a genetically-

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82. *See* Howard W. Jones, Jr., *Reflections on the Usefulness of Embryo Cloning*, 4 KENNEDY INST. ETHICS J. 205, 206 (1994).

83. *See id.*

84. *See* NABER, *supra* note 7, at 255.

85. *See* Cohen & Tomkin, *supra* note 4, at 199.

86. *See id.*

87. *See id.* at 200.

88. *See* NABER, *supra* note 7, at 254.

89. *See id.*

90. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 13-14.

related child.[91] Absence of a male germline among female homosexual couples could likewise be overcome using nuclear transfer of an adult cell, providing even these couples with genetic offspring.[92] In either case, the resulting child would inherit a genetic tie with one rearing parent, the nucleus donor, a second genetic tie, through mitochondrial genes, with the egg donor, and a biologic tie, through gestation, with a rearing mother.[93]

Although not as widespread as infertility problems, genetic diseases could be entirely avoided through cloning technology. Mitochondrial diseases, which are inherited only in the maternal line, can produce severe muscular, neurological, and metabolic diseases and sometimes blood diseases.[94] Because the nucleus of an embryonic cell is free from mitochondrial genes, it can be injected into the healthy enucleated egg of another woman to direct normal embryonic development.[95] After the egg is implanted, presumably into the womb of the nucleus donor, the new embryo can develop with the egg donor's mitochondrial genes. Because mitochondrial genes represent an extremely small percentage of the total number of mammalian genes, the resulting embryo's genetic makeup should substantially match that of the original embryo, reflecting the combined genome of its progenitors, not that of the egg donor.[96] Thus, in this application of cloning technology, only the resulting embryo will be implanted, not the original embryo, a fact that has led at least one commentator to conclude that a child created in this way is not really a clone of anyone.[97]

Beyond mitochondrial diseases, many of the genetic diseases inherited by an embryo could be prevented through nuclear transfer of genetic material from an adult cell. For couples who consider the use of donated gametes unacceptable but who cannot procreate without a substantial risk of passing on debilitating genetic diseases, the nuclear transfer of a somatic cell from one of the adults could permit the creation of an embryo unaffected by the deleterious genes of one or both parents.[98] Such parents, faced with the difficult decision between using prenatal diagnosis and selective abortion or burdening their child with a debilitating genetic disease, would thus have the option of using DNA

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91. *See* NBAC REPORT, *supra* note 1, at 31.

92. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 14.

93. *See* Axel Kahn, *Clone Mammals . . . Clone Man?*, 386 NATURE 119 (1997).

94. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 16. Disorders of mitochondrial function include defects of pyruvate metabolism, fatty acid oxidation, the Krebs cycle, and the electron transport chain. *See Center for Inherited Disorders of Energy Metabolism* (School of Med., Case W. Reserve Univ.) (last modified Aug. 25, 1997) <http://www.cwru.edu/med/CIDEM/cidem.htm>.

95. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 16.

96. *See* NBAC REPORT, *supra* note 1, at 20.

97. *See* Kahn, *supra* note 93, at 119.

98. *See* NABER, *supra* note 7, at 271.

derived from only one progenitor to clone a genetically healthy embryo.[99] Moreover, nuclear transfer used in this way, like existing practices of egg or sperm donation, would still ensure the child of a genetic tie with one rearing parent and a biological tie, through gestation, with the rearing mother. In this particular context, at least, the use of cloning does not radically or essentially differ from current medical practices.[100]

In some instances, parents and their physicians may be unable to ascertain an embryo's risk of genetic disease without genetic testing. In such cases, preimplantation genetic diagnosis may be performed *in vitro* by removing one blastomere cell to test its genetic structure.[101] If the tests show that the embryo is healthy, it can be implanted, notwithstanding the missing cell.[102] By permitting the preimplantation genetic diagnosis and discard of abnormal embryos, parents who do not desire to give birth to a genetically abnormal embryo can avoid the more difficult choice of abortion once the embryo is implanted.[103] At present, however, physicians can only sample one cell from the embryo because the removal of additional cells will considerably diminish embryo survival.[104] Moreover, the small sample size inherent in the present method results in an improper diagnosis thirty-three percent of the time.[105] Cloning would make available a larger supply of cells for sampling, thus improving the chances that a healthy pregnancy will result,[106] but in some cases the testing itself would destroy the embryos that were cloned for the specific purpose of diagnosis.[107] This result is not incongruous with the result presently obtained in reproductive medicine. Current assisted reproductive practices routinely permit the destruction or degeneration of cryogenically preserved embryos once the delivery of a healthy baby has occurred. One ethicist has stated,

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99. *See* NBAC REPORT, *supra* note 1, at 78-79.

100. *See Ethics and Theology: A Continuation of the National Discussion on Human Cloning: Hearings on S. 368 Before the Subcomm. on Pub. Health and Safety of the Senate Comm. on Labor and Human Resources*, 105th Cong. 47-48 (1997) (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law) [hereinafter *Ethics and Theology*].

101. *See* NBAC REPORT, *supra* note 1, at 32.

102. *See* NABER, *supra* note 7, at 262.

103. *See id.* at 269.

104. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 13.

105. *See* NABER, *supra* note 7, at 262.

106. *See id.* at 263, 269.

107. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 13.

> It is self-deception to imagine that the 10,000 or more existing cryopreserved embryos will eventually be implanted. It is also folly to suppose that every time a couple decides to freeze three or four or seven embryos resulting from IVF they really intend to implant them at some time in the future.[108]

If the cloned embryos would be destroyed anyway, their destruction through preimplantation genetic diagnosis would at least produce some benefit to the prospective parents.

In addition to its potential to overcome sterility and guard against genetic disease, cloning could be used to provide the parents of an existing child with an identical younger sibling, a delayed genetic twin.[109] This could result either from the nuclear transfer of genetic material from the existing child or from the prior cryogenic preservation of an embryo produced through blastomere separation—that is when the cell that gave rise to it was separated from the cells that gave rise to the existing child. Some may wish to create an identical child, using cryogenically preserved embryos or the nucleus of a child, to attempt to replace a child who is dying or has already died.[110] Of course, the new child cannot be the child who was lost. Non-genetic factors such as brain development after birth, interpersonal relationships, and parenting techniques will determine who the new child is and will make him or her different in personality from the deceased child.[111]

Still other parents might wish to have a delayed genetic twin who will serve as a donor of non-vital organs, tissues, or bone marrow to satisfy the medical needs of the existing child.[112] The fact that an estimated 50 to 100 couples in recent years who have produced babies to provide genetically compatible tissue for an existing child demonstrates the likelihood that couples will use cloning technology for this purpose.[113] Conversely, it is unlikely that couples would use blastomere separation, IVF, and cryogenic preservation solely to gain hypothetical protection for a future child because of the risks inherent in these processes.[114]

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108. Macklin, *supra* note 9, at 221-22.

109. *See* Stephen A. Newman, *Human Cloning and the Family: Reflections on Cloning Existing Children*, 13 N.Y.L. SCH. J. HUM. RTS. 523, 524 (1997).

110. *See id.* at 525.

111. *See id.* at 529.

112. *See* NABER, *supra* note 7, at 261.

113. *See* Barbara Ehrenreich, *The Economics of Cloning*, TIME, Nov. 22, 1993, at 86.

114. *See* NABER, *supra* note 7, at 261.

The nuclear transfer technique, on the other hand, could be used to create an identical embryo at any time in the life of an adult or child and without prior cryogenic preservation. It would therefore be possible to satisfy the medical needs of any patient by creating a genetic twin to donate genetically matched organs, tissues, or bone marrow.[115] Nonetheless, those wishing to use either method of cloning to create a donor are likely to find that the patient's existing transplant needs cannot wait until the cloned embryo has sufficiently developed to serve safely as an organ or tissue donor.[116]

Some individuals may, therefore, use the genetic material of an identical twin for the benefit an existing child, or even for themselves, without regard for the safety of the cloned embryo. The embryo thus produced could be implanted and used as a source of fetal tissue, organs, or ovaries after its development was arrested.[117] Currently, fetal tissue therapies and organ and ovary transplantation therapies are still in the experimental stage and are not available to treat human patients.[118] However, if performed, this practice would raise issues analogous to those arising from the present uses made of fetal tissues following an abortion. One group of ethicists has noted that such an application of cloning technology would conflict with established social constraints: "The scenario in which a cloned embryo would be brought to life and later killed so as to harvest its organs to use in an identical twin is preposterous, given the strong legal and moral prohibitions . . . against taking another's life."[119]

However, recent discoveries indicate that it will be unnecessary to clone whole organisms or embryos in order to meet the needs for organ and tissue donation. As discussed above, learning to direct gene expression in particular cells will allow scientists to control cell differentiation and produce various tissues and organs. For instance, scientists in England recently produced headless frog embryos by manipulating the genes in frog eggs, and they have used the same technique to suppress development of tadpoles' trunks and tails.[120] As this technology develops and is combined with nuclear transfer cloning, headless human clones could be created to grow organs and tissues for transplantation. Scientists believe the technique could eventually be adapted to grow human organs in an embryonic sac living in an artificial womb. Creating headless clones to grow organs would bypass some legal restrictions and ethical

115. *See* NBAC REPORT, *supra* note 1, at 30.

116. *See* NABER, *supra* note 7, at 261.

117. *See* COMITÉ, SCIENTIFIC AND TECHNICAL ASPECTS, *supra* note 5, at 14.

118. *See* NABER, *supra* note 7, at 272.

119. *Id.*

120. *See* Steve Connor & Deborah Cadbury, *Headless Frog Opens Way for Human Organ Factory*, TIMES (London), Oct. 19, 1997 <http://www.the-times.co.uk/news/pages/sti/97/10/19/stinwenws01019.html?2237033>.

concerns regarding the creation of embryos—by definition, these entities would not be persons or embryos because they would not have brains or central nervous systems.[121] In a very real sense, then, using cloning technology to produce headless clones or groups of organs would not result in cloned humans at all.

IV. MORAL AND ETHICAL CONSIDERATIONS REGARDING THE USE OF CLONING TECHNOLOGY TO PRODUCE HUMANS

Although the ethical issues surrounding human cloning technology can easily become enmeshed in the broad ethical issues surrounding the use of embryos in scientific research, the ethical issues unique to human cloning arise only when the technology is used to create a child.[122] Some individuals believe that human cloning is inherently wrong and would be immoral under any circumstances. Others consider cloning a morally neutral technology and consider cloning humans ethically problematic only when the technology is used in certain ways.[123] In all of the cases in which the latter individuals consider human cloning justified, they presuppose that three basic criteria have been established: that the procedure can be performed without harming the child created by cloning, that the child's rights and interests will be protected, and that no other acceptable alternatives to cloning could produce the ends sought.[124]

A. Arguments Regarding Physical and Psychological Risks

The first group of objections to human cloning relate to the physical and psychological risks to which a clone may be subjected. The possibility that, because of insufficient knowledge, laboratory mistakes could lead to the birth of seriously injured children or subhuman creatures causes some individuals to conclude that cloning should never be attempted.[125] With respect to somatic cell nuclear transfer in particular, opponents of human cloning are quick to point out the low success rate in the cloning of the sheep Dolly—only one lamb after

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121. *See id.*

122. *See Ethics and Theology, supra* note 100, at 39 (statement of Ezekiel J. Emanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

123. *See id.* at 9 (statement of James F. Childress, Professor of Med. Educ. and Co-Director, Va. Health Policy Ctr., Univ. of Va.).

124. *See id.* at 6.

125. *See* NABER, *supra* note 7, at 259-60.

276 failed attempts.[126] Limited information about the results of nuclear transfer could create two physical risks that could affect the normal development of a clone. Because normal cells undergo a defined number of cell divisions before they senesce, scientists hypothesize that a clone's cells may age prematurely.[127] Further, scientists speculate that cumulative nuclear mutations may lead to cancer, deformities, and diseases in offspring.[128]

Because nuclear transfer would not be performed for its therapeutic benefit to the clone, those who desire to protect human clones from these risks would require heightened evidence of the technique's safety and effectiveness in animal and cellular models as a condition precedent to human applications of these techniques.[129] However, even without regulation, human applications of these techniques are unlikely to occur before extensive animal research establishes their safety and efficacy.[130] With regard to blastomere separation, at least, experience with cattle suggests that concern over physical risks to humans is unfounded.[131]

Moreover, imposing stricter standards on cloning techniques as opposed to other reproductive techniques may be unwarranted. Proponents of cloning note that prospective parents may lawfully conceive and give birth to children despite substantial known risks that such children will inherit genetic diseases. The NBAC noted: "Since many of the risks believed to be associated with somatic cell nuclear transfer may be no greater than those associated with genetic disorders, some contend that such cloning should be subject to no more restriction than other forms of reproduction."[132] In both contexts, it can be argued that the benefits of being brought into existence outweigh the risks of resulting genetic harms. Characterized in this way, any method of assisted reproduction that results in a child should be classified as experimentation for the child's benefit.[133] In addition, the actual risks of physical harm that nuclear transfer poses to human clones cannot be accurately predicted until the

126. *See* NBAC REPORT, *supra* note 1, at 65. Similarly, embryonic nuclear transfer has resulted in developmental abnormalities or death in 60% of the lambs produced through this technique. *See Scientific Discoveries, supra* note 29, at 22 (statement of Ian Wilmut, Embryologist, Roslin Inst., Edinburgh, Scotland).

127. *See Ethics and Theology, supra* note 100, at 37 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med. Harvard Med. Sch.).

128. *See id.*

129. *See id.*

130. *See id.* at 48 (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law). "Couples interested in using cloning to form a family would have little interest in a technique that led to physical defects in children." *Id.*

131. *See* Cohen & Tomkin, *supra* note 4, at 200.

132. NBAC REPORT, *supra* note 1, at 65.

133. *See id.* at 65-66.

technique has been performed on human beings: "if we insisted on absolute guarantees of no risk before we permitted any new medical intervention to be attempted in humans, this would severely hamper if not halt completely the introduction of new therapeutic interventions, including new methods of responding to infertility."[134]

Concerns about the physical risks posed to the human clone are augmented by concerns relating to his or her psychological well-being. In particular, opponents of human cloning contend that this form of reproduction would undermine the autonomy and individuality of children created from an older twin.[135] As the NBAC report suggests, "[i]n this line of reasoning, ignorance of the effect of one's genome on one's future is necessary for the spontaneous, free, and authentic construction of a life and self."[136] This problem does not arise in applications of cloning that produce contemporaneous twins, because each begins life ignorant of what the twin who shares the same genome will make of his or her life. A delayed genetic twin, however, may go through life burdened with the feeling that another has already played out important life choices.[137] Despite the fact that a combination of genetic and environmental influences would shape a clone's character and development, if the clone believes and others behave as though the previously existing twin significantly determined the future of the later twin, the clone's choices would not really be free.[138]

Proponents of human cloning, in contrast, contend that a clone's future would be no less open because he or she shares DNA with another individual. Professor John A. Robertson has argued, "The fact that we can glimpse something of our future by looking at persons with similar genes doesn't prevent us from making and choosing our futures as we live our lives."[139] Some have noted the speculative and value-laden nature of arguments concerned with protecting a clone's autonomy and individuality. The younger twin may not believe that his or her future is really constrained and, in any event, could not legitimately believe so. The argument may simply not apply if the belief is false and can be shown to be false.[140]

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134. *Id.* at 66.

135. *See Ethics and Theology, supra* note 100, at 36 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

136. NBAC REPORT, *supra* note 1, at 66.

137. *See Ethics and Theology, supra* note 100, at 37 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

138. *See id.*

139. *Id.* at 49 (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law).

140. *See* NBAC REPORT, *supra* note 1, at 67.

B. Arguments Regarding Social Worth

Related to concerns that human cloning will diminish autonomy are concerns that the loss of genetic uniqueness will lessen the social worth of clones. Cloning, contend critics, may lessen respect for clones, as well as for persons in general, because cloning will instill the notion that individuals can be replaced.[141] Those who advance this argument, however, must recognize that what distinguishes one human being from another is the unique pattern of roles and relationships each enjoys and not the dissimilarity of one body from others.[142] One group of ethicists has stated that "the occurrence of identical twins and triplets in nature does not appear to diminish societal respect for the value of human beings."[143] Moreover, both common experience and psychology teach that identical twins have distinctively different personalities.[144] It has been noted, "Even identical twins who grow up together and thus share the same genes and a similar home environment have different likes and dislikes, and can have very different talents."[145] Like identical twins that result from natural processes, clones will have as much individual value to parents, friends, spouses, and children as do individuals who are genetically unique.[146]

In addition, individuals created through cloning may not be as identical as naturally-occurring identical twins. In nuclear transfer, development may be affected by the egg cytoplasm.[147] In both nuclear transfer and blastomere separation, epigenesis in development will give otherwise identical twins different organizations within their cerebral and immune systems.[148] Indeed, one commentator has argued that "variations in gestational environment and upbringing ensure that the cloning of identical genetic material does not result in identical persons."[149] The cultural and social environment existing at the time when a particular clone is born would further enhance psychological uniqueness.[150] Moreover, the aging process will cause differences in the

141. *See* NABER, *supra* note 7, at 256.
142. *See* Macklin, *supra* note 9, at 218.
143. NABER, *supra* note 7, at 267.
144. *See* Macklin, *supra* note 9, at 217.
145. NBAC REPORT, *supra* note 1, at 33.
146. *See* Macklin, *supra* note 9, at 216.
147. *See id.* at 217.
148. *See* COMITÉ CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (Fr.) [NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES, REP. NO. 54: REPLY TO THE PRESIDENT OF THE FRENCH REPUBLIC ON THE SUBJECT OF REPRODUCTIVE CLONING: ETHICAL CONSIDERATIONS 2-3 (Apr. 22, 1997) <http:// www.ccne-ethique.org/ccne_uk/avis/a_054.htm>.
149. *Scientific Discoveries, supra* note 29, at 49 (statement of Karen H. Rothenberg, Professor of Law and Director, Law and Health Care Program, Univ. of Maryland Sch. of Law).
150. *See* Kahn, *supra* note 93, at 119.

appearance of identical individuals of different ages so that identical twins separated by a generation of time may not even recognize themselves in one another.[151]

C. *Arguments Regarding Human Dignity*

Those who defend the rights of individuals created through cloning often argue in terms of the need to protect human dignity. Such arguments stress simultaneously the sanctity of all human life and the equality of cloned individuals to other persons.[152] Some individuals, concerned that human cloning may interfere with the sanctity of life, condemn cloning as *per se* ethically impermissible because it subjects human individuals, at their most vulnerable state, to the power and manipulation of others.[153] Others feel that particular applications of human cloning do not impinge upon the sanctity of life as long as cloning technology is used in support of life.[154]

Notably, religious thinkers on both sides of the issue consider human clones to be humans created in the image of God and extend to such individuals the same freedom and moral agency that apply to all individuals.[155] Therefore, these religious thinkers would oppose any application of cloning technology that would make clones into slaves or deny their equal status among humanity. Nevertheless, opponents of human cloning argue that cloning encourages society to view children as objects to be used rather than as gifts to be cherished.[156] Creating identical embryos to improve the chances of reproducing one child from among several replaceable copies, they contend, necessarily treats embryos as interchangeable products, rather than as the forerunners of individuals.[157] As one commentator pointed out, "[t]he Kantian maxim that persons must be seen as ends in themselves, as well as our general social ethic of respect for persons as individuals, warns against . . . harm[ing] one person in order to benefit others."[158]

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151. *See* NABER, *supra* note 7, at 258.

152. *See* NBAC REPORT, *supra* note 1, at 49.

153. *See id.* at 50.

154. *See id.* The latter individuals, however, understand that those utilizing these techniques must accept and care for human clones created, even those who do not develop as expected due to technological shortfalls. *See id.*

155. *See id.* at 43, 49.

156. *See Ethics and Theology, supra* note 100, at 41 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

157. *See* NABER, *supra* note 7, at 257.

158. *Id.* at 262.

For example, cloning individuals solely for research, genetic testing, or the preparation of spare tissues and organs would violate this principle.[159] On the other hand, using cloning to combat sterility, has as its explicit goal the creation of a life with human dignity. Because the mere creation of a human clone does not necessarily deny equality of treatment to the created individual, those in favor of permitting some applications of human cloning believe that this use of cloning would not violate human dignity.[160]

Others contend that human cloning, even for reproductive purposes, would be performed not for the clone's benefit but to satisfy the objectives of someone else:[161]

> When such cloning is undertaken not for any purported benefit of the child himself or herself, but rather . . . to serve the need of someone else, such as a dying child in need of a bone marrow donor, then some would argue that it goes yet another step toward diminishing the personhood of the child created in this fashion.[162]

Once the intrinsic value of individuals is compromised, their possession of certain desirable characteristics determines their worth.[163] Clones may be created "to be like a beloved child that died, or to be a genetic match for an organ transplant, or to express the mathematical or musical qualities of an exceptional person."[164] Those persons who clone using the nucleus of mature cells will likely choose particular DNA because of its significance to them, such

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159. *See id.* at 262-63 (highlighting problems with embryo destruction in embryo splitting experiments). According to Alex Kahn, the objective of "[c]reating human life for the sole purpose of preparing therapeutic material would clearly not be the dignity of the life created." Kahn, *supra* note 93, at 119.

160. *See* Kahn, *supra* note 93, at 119.

161. *See Ethics and Theology, supra* note 100, at 41 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

162. NBAC REPORT, *supra* note 1, at 74.

163. *See id.*

164. *Ethics and Theology, supra* note 100, at 41 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

as its favorable expression in a living, breathing person.[165] Rearing parents may have rigid or unrealistic expectations about children so created precisely because of the genome chosen.[166] Although cloned children may not achieve these expectations, those endeavoring to create children with specific characteristics may value the children instrumentally rather than intrinsically, to the extent that their expectations are met.[167]

If parents view their children as products, their desire to control the qualities of their children may diminish their capacity to provide their children with the immeasurable care and nurture inherent in normal parent-child relationships.[168] As John Robertson suggests, "[t]hey could end up disappointed in the child, or embark on a socialization or rearing process to shape the child according to its genes, thus denying the child its own autonomy and individuality."[169] In addition, commercial and economic forces could transform objectification of clones into commodification, as the marketplace shapes the utility and consequent worth of individuals created through cloning.[170] If left unregulated, cloning could lead to commercial clone catalogs containing pictures and information about children whose duplicates are offered for sale.[171]

These arguments may be more persuasive when applied to particular forms of cloning than when applied to cloning in general. Upon closer scrutiny, arguments rooted in the concept of human dignity rely upon an underlying concern with the control that parents will have because they can foresee the results of the child's genetic makeup. Karen Rothenberg noted: "Unlike reproductive technology involving only embryos, the cloning of adult cells permits us to see a grown manifestation of the genetic material we are cloning. That knowledge makes genetic selection possible."[172] In the context of natural procreation, the inability of parents to foresee the results of genetic inheritance protects the newly created individual's autonomy, an essential element of human

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165. *See Scientifics Discoveries, supra* note 29, at 48 (statement of Karen H. Rothenberg, Professor of Law and Director, Law and Health Care Program, Univ. of Maryland Sch. of Law).

166. *See Ethics and Theology, supra* note 100, at 49 (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law).

167. *See id.* at 41 (statement of Ezekiel J. Emmanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

168. *See* Allen D. Verhey, *Cloning: Revisiting an Old Debate*, 4 KENNEDY INST. ETHICS J. 227, 232 (1994).

169. *Ethics and Theology, supra* note 100, at 49 (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law).

170. *See* NBAC REPORT, *supra* note 1, at 50.

171. *See* NABER, *supra* note 7, at 260.

172. *Scientific Discoveries, supra* note 29, at 50 (statement of Karen H. Rothenberg, Professor of Law and Director, Law and Health Care Program, Univ. of Maryland Sch. of Law).

dignity.[173] However, as with natural procreation, cloning techniques, such as blastomere separation, that do not involve somatic cell nuclear transfer from an already-born individual create a person whose characteristics cannot be foreseen or made to depend upon another person's will.

Furthermore, notwithstanding the ability of parents to foresee the genetic inheritance of the resulting embryo, the nuclear transfer of genetic material from an adult cell may pose no greater danger of making children into manipulable objects than current practices, such as genetic screening, that endeavor to avoid creation of a child with a particular condition. To the extent that parents use such technology to benefit the child ultimately created, no objectification of the child takes place.[174] Finally, proponents of cloning argue that children whose DNA has been intentionally chosen are no more likely to be endangered by unrealistic parental expectations than other children who are deeply invested with parental hopes and desires.[175] Parental expectations, even if unmet, do not necessarily diminish the extent to which parents extend unconditional love to their children.

Inasmuch as others have access to any individual's body cells, nonconsensual nuclear transfer could infringe upon the rights of existing adults as well as children, thus violating human dignity in a different sense. Lori Andrews has noted, "Under current law, people have very little control over what's done with their genetic material, and probably would be very limited in the sort of action they could bring based on products that were made, including individuals, out of their tissue."[176] To the extent that voluntary participation is necessary to moral human reproduction, nuclear transfer of a cell from an existing child, or any other individual unable or unwilling to consent, would be a *per se* violation of the cell donor's fundamental right not to reproduce.[177]

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173. *See* COMITÉ CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (Fr.) [NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SCIENCES], REP. NO. 54: REPLY TO THE PRESIDENT OF THE FRENCH REPUBLIC ON THE SUBJECT OF REPRODUCTIVE CLONING: CONCLUSION 1 (Apr. 22, 1997) <http://www.ccne-ethique.org/ccne_uk/avis/ethique.org/ccne_uk/avis/a_054.htm>.

174. *See* NBAC REPORT, *supra* note 1, at 73.

175. *See Ethics and Theology*, *supra* note 100, at 49 (statement of John A. Robertson, Professor of Law, Univ. of Tex. Sch. of Law). "[Q]uite normal parenting usually involves many constraints on a child's behavior that children may resent." NBAC REPORT, supra note 1, at 68.

176. *The Clone Age*, A.B.A. J., July 1997, at 68, 72 (quoting Lori Andrews).

177. The Supreme Court has not yet decided whether individuals have a fundamental right to avoid genetic parentage. However, the Court has recognized individuals' fundamental right to use contraceptives in procreation. *See* Griswold v. Connecticut, 381 U.S. 479, 484 (1965) (recognizing a fundamental right to privacy that is violated when a state prohibits a married couple's use of contraceptives). *See also* Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) (extending the right to privacy to encompass freedom of all individuals from unwarranted governmental intrusion into the decision of whether to bear a child). Governmental regulations that burden this right will be

To comport with the moral and legal principle of equality, no individual should be able to exercise such dominion over another individual.[178]

Like other objections to cloning mentioned above, this argument becomes meaningless when applied to the cloning techniques of embryonic nuclear transfer and blastomere separation, because these techniques do not create individuals from cells of already-born individuals. In such cases, lack of consent would not infringe upon any individual's dignity.

D. Arguments Regarding Individual Rights

Balanced against the alleged harms of human cloning are considerations of individual rights. American law presumes in favor of personal autonomy thus preventing governmental prohibition or regulation of personal activities absent strong arguments to the contrary, such as the common good and the need to protect others from harm.[179] For example, the NBAC noted: "Where the individual actions are expressions of fundamental rights, such as the right to free speech or the right to privacy, the reasons for limitation must be compelling, and the limitations made as minimal as possible."[180] While it is unclear whether the right to privacy includes the freedom to clone, if cloning is treated as a fundamental right, the courts would apply the strict scrutiny standard in considering any governmentally imposed regulation of human cloning.[181]

While the Supreme Court has not explicitly recognized the right to procreate,[182] the Court has articulated a right of privacy that extends procreative liberty to all individuals, regardless of marital status.[183]

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subjected to strict scrutiny. *See* Carey v. Population Servs. Int'l, 431 U.S. 678, 688 (1977) (holding that state regulations that burden an individual's right to decide to prevent conception may be justified only by a compelling state interest, and they must be narrowly drawn to express only the state's legitimate interest).

178. *See Scientific Discoveries, supra* note 29, at 43 (statement of George J. Annas, Professor and Chair, Health Law Dep't, Boston Univ. Sch. of Pub. Health).

179. *See* NBAC REPORT, *supra* note 1, at 8, 76, 91. *See also* Jacobson v. Massachusetts, 197 U.S. 11, 29 (1905) (recognizing that governmental interference with an individual's ability to assert the supremacy of his own will may only be justified by the need to protect the public health, safety, and welfare).

180. NBAC REPORT, *supra* note 1, at 8. *See* Shapiro v. Thompson, 394 U.S. 618, 634 (1969) (explaining that any law that serves to penalize the exercise of a constitutional right, unless shown to be necessary to promote a compelling governmental interest, is unconstitutional).

181. *See* NBAC REPORT, *supra* note 1, at 95.

182. Because no state law restricts individuals from having children, the Court has not yet had to directly rule upon the issue.

183. *See* Eisenstadt v. Baird, 405 U.S. 438, 453 (1972). *See also* Planned Parenthood v. Casey, 505 U.S. 833, 851 (1992) (reaffirming the constitutional protection accorded to reproductive decisions).

Concerning an infertile couple's decision to undergo medically assisted reproduction, one federal district court has held, "It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."[184]

Opponents of human cloning argue that rights regarding reproductive freedom do not encompass cloning.[185] They contend that, unlike other assisted reproductive technologies, somatic cell nuclear transfer is not merely a remedy for an individual's inability to reproduce sexually but an alternative, asexual means of reproduction.[186] On the other hand, both blastomere separation and embryo nuclear transfer require the voluntary sexual participation of two individuals to create the original embryo, and, like the widely accepted practices of IVF and sperm and egg donation, all of the cloning techniques facilitate the ability to reproduce.[187] If these techniques can be used to serve reproductive ends, argue proponents, they should be available as reproductive technologies and legally protected.[188]

Moreover, a particular cloning technique may provide the only means of reproduction for some individuals. In such a situation, the individual's interest in reproductive freedom weighs most heavily against opposing interests.[189] Proponents of human cloning argue that only compelling reasons, such as serious harm to third parties, should suffice to limit the practice. If a cloning technique does not cause harms qualitatively different from currently used practices of assisted reproduction and genetic selection, it should be no less legally available as an alternative for infertile couples.[190]

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184. Lifchez v. Hartigan, 735 F. Supp. 1361, 1377 (N.D. Ill.), *aff'd without opinion sub nom.* Scholberg v. Lifchez, 914 F.2d 260 (7th Cir. 1990), *cert. denied*, 498 U.S. 1068 (1991).

185. *See Scientific Discoveries*, *supra* note 29, at 44 (statement of George J. Annas, Professor and Chair, Health Law Dep't, Boston Univ. Sch. of Pub. Health).

186. *See* NBAC REPORT, *supra* note 1, at 77.

187. *See id.* at 77, 78.

188. *See id.* at 95.

189. *See id.* at 78.

190. *See Ethics and Theology*, *supra* note 100, at 48. "Since there are no serious harms to third parties from cloning human beings, and what harms may exist are too speculative and unproven, cloning should be permitted." *Id.* at 39 (statement of Ezekiel J. Emanuel, Member, Nat'l Bioethics Advisory Comm'n and Faculty Member, Dep't of Soc. Med., Harvard Med. Sch.).

V. GOVERNMENTAL REACTIONS TO THE POSSIBILITY OF HUMAN CLONING

A. The Council of Europe

The Council of Europe has long insisted that biological and genetic research and clinical applications remain consistent with a fundamental commitment to human dignity.[191] This intergovernmental organization recently promulgated a multinational convention on human rights and biomedicine, which, *inter alia,* provides that signatory nations "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."[192] Even those non-signatory European nations will likely be influenced by the convention, which should provide a framework to guide medical research and practice throughout Europe.[193]

The convention's broad and somewhat vague mandate, a necessary result of the compromise that produced it, may prove to be more inclusive of cloning techniques than the narrow, scientific definitions often found in national legislation. Although the convention does not expressly forbid human cloning, inasmuch as the signatory countries view the prospect of human cloning as incompatible with human dignity, their laws will be modified or interpreted to prohibit the practice.[194] Conversely, to the extent that these nations recognize a fundamental right to reproduce, the convention's language obligates them to guarantee individuals freedom in utilizing biomedical reproductive techniques that do not impinge upon the human dignity of individuals thus created.[195] Thus, the judgment of national legislatures will determine which cloning techniques will be proscribed. The French government, for example, would interpret the convention to ban human cloning but also admits that this interpretation is debatable.[196] A French agency charged with analyzing the

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191. *See* NBAC REPORT, *supra* note 1, at 3.

192. Council of Europe, Convention on Human Rights and Biomedicine, Apr. 4, 1997, art. 1, ¶ 1 (visited June 17, 1998) <http://www.tufts.edu/departments/fletcher/multi/texts/biomed.txt> [hereinafter Convention]. Since April 1997, at least 22 of the Council of Europe's 40 member nations have signed the convention, committing themselves to making their laws compatible with the principles contained in the document. *See* F. William Dommel, Jr., & Duane Alexander, *The Convention on Human Rights and Biomedicine of the Council of Europe,* 7 KENNEDY INST. ETHICS 259, 259 (1997).

193. *See* Dommel & Alexander, *supra* note 192, at 259-60.

194. *See* NBAC REPORT, *supra* note 1, at 103.

195. *See* Convention, *supra* note 192, at art. 1, ¶ 1.

196. *See* COMITÉ CONSULTATIF NATIONAL D'ETHIQUE POUR LES SCIENCES DE LA VIE ET DE LA SANTÉ (Fr.) [NATIONAL CONSULTATIVE ETHICS COMMITTEE FOR HEALTH AND LIFE SERVICES], REP. NO. 54: REPLY TO THE PRESIDENT OF THE FRENCH REPUBLIC ON THE SUBJECT OF REPRODUCTIVE CLONING: LEGAL CONSIDERATIONS 6 (Apr. 22, 1997) <http://www.ccne-ethique.org/ccne_uk/avis/a_054.htm> [hereinafter COMITÉ, LEGAL CONSIDERATIONS].

regulation of human cloning concluded, "It therefore seems essential that an addition should be made in some appropriate form to complete this international instrument with a view to prohibiting reproductive cloning."[197]

Specific language in the convention will, nonetheless, limit certain applications of cloning technology. For example, the convention prohibits the creation of embryos for research purposes and requires that other embryos subject to research be adequately protected from harm.[198] These provisions would apply regardless of whether the research is conducted in the public or private sectors.[199] Notably, the convention's language does not amount to a ban on the use of embryos for research purposes. With blastomere separation and nuclear transfer, identical embryos developed to facilitate reproduction need not all be implanted. Because such embryos would not be created for research purposes, *in vitro* research on the remaining embryos need not violate the convention's terms as long as the embryos are adequately protected.[200] Similarly, by prohibiting the use of human bodies and their parts for financial gain, the convention requires protection of embryos from those who would profit from their sale.[201] While this provision is not specifically directed at the sale of cloned embryos, it would explicitly prevent such practices.

Another section of the convention bans interventions seeking to modify the human genome when they aim "to introduce any modification in the genome of any descendants."[202] This section may be interpreted to prohibit the use of cloning to modify the genetic inheritance of a cloned embryo, even though the scientists, doctors, or others may be attempting to avoid genetic disease. However, this result seems contrary to the section's overall intent which permits the modification of the human genome for preventive, diagnostic, or therapeutic purposes.[203] If the aim of the intervention were an effort to directly introduce the modification into the newly created clone, with only incidental benefits flowing to the clone's descendants, perhaps this section would not then prohibit the use of cloning techniques to avoid genetic diseases. This result harmonizes with the other language in the convention that permits the use of assisted reproductive technology to determine a future child's sex when a "serious hereditary sex-related disease" might burden the child.[204]

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197. *Id.*
198. *See* Convention, *supra* note 192, at art. 18, ¶¶ 1-2.
199. *See* Dommel & Alexander, *supra* note 192, at 273.
200. *See* Convention, *supra* note 192, at art. 18, ¶ 1.
201. *See id.* at art. 21, ¶ 1.
202. *Id.* at art. 13, ¶ 1.
203. *See id.*
204. *See id.* at art. 14, ¶ 1.

The convention also implicitly bans the use of cloned embryos as donors of non-regenerative tissue. The convention further requires that the removal of regenerative tissue from clones, who are unable to give consent, be limited to circumstances in which a compatible donor, who has the capacity to consent, is unavailable and the clone's tissue is necessary to save the life of a "brother or sister."[205] The convention's language is not clear as to whether an emancipated child or adult could be cloned in the interest of saving that individual's life. Because the resulting clone would not be raised as a brother or sister of the tissue recipient, the convention arguably would prohibit cloning in this context, yet it seems somewhat arbitrary to use clone tissue to benefit only those individuals living with their parents. By definition, a clone would be related as an identical sibling to the individual who shares his or her genetic identity. This is true regardless of whether the clone is reared together with, apart from, or as a child of the individual who receives the clone's tissue. If the convention's language were interpreted based upon genetic identity, using a clone's regenerative tissue to assist any individual who shares the clone's genome could not be prohibited as a *per se* violation of human dignity.

B. France

Some European countries have taken a markedly different approach. France, a member of the Council of Europe, was one of the first nations to sign the convention described above.[206] As mentioned above, the French government would prefer that the convention prohibit human cloning expressly and already interprets the convention to require nations subject to it to follow its lead. A French agency charged with examining the sufficiency of French law in this area has concluded that no new laws would be necessary to ban human cloning in France.[207]

The agency determined that, although French laws do not specifically refer to human cloning, the use of cloning in humans is prohibited by Article 16-4 of the *Code Civil,* Articles 511-1 and 511-18 of the *Code Pénal,* and Articles L. 152-1, L. 152-2, L. 152-3, and L. 152-8 of the *Code de la Santé Publique* (Code of Public Health).[208] Article 16-4 of the *Code Civil* provides: "Without prejudice to research for the prevention and treatment of genetic diseases, no modification can be made to genetic traits with the purpose of

205. *See id.* at art. 20, ¶¶ 1-2.

206. *See* Dommel & Alexander, *supra* note 192, at 259.

207. *See* COMITÉ, LEGAL CONSIDERATIONS, *supra* note 196, at 4. "The law, as it stands now . . . condemns reproductive cloning of a human being. There is no need for new legislation except for purposes of clarification." *Id.*

208. *See id.* at 1-4.

modifying the descent of a person."[209] All methods of cloning, the French agency contends, are genetic modifications undertaken with the aim of modifying the descent of a person, notwithstanding the fact that the result of the medical intervention preserves the genetic heritage of the cell from which it was derived.[210] To reach this conclusion under the language of the law, the agency apparently decided that cloning modifies genetic traits; this decision may be warranted by the fact that the human alteration of genetic raw material required for cloning deprives the original cells of their natural progress. With blastomere separation, the human intervention deprives the embryonic cells so isolated from their natural union. With nuclear transfer, human intervention actually alters the cells to permit their fusion and enucleates the recipient egg so that it can no longer transmit its genetic heritage.[211]

Even if medical intervention is a means of genetic modification, however, Article 16-4 does not proscribe it unless it is performed to modify an individual's descent. The French agency argues that cloning necessarily has this result, because cloning involves reproduction without the fusion of gametes of two members of the opposite sex. One French commentator has noted: "Since the human species was established by sexual reproduction, to so fundamentally modify the mode of transmission of the genome would mar the integrity of the species."[212] Moreover, Article 16-4 expressly prohibits "[a]ny eugenic practice with a view to organising a selection of persons."[213] Because cloning requires genetic material to be chosen from an existing embryo, child, or adult, cloning could reasonably be characterized as aimed at selection of persons, and thus prohibited. Further, Article 511-1 of the *Code Pénal* would criminalize conduct not conforming with Article 16-4. However, genetic modifications that facilitate research for the prevention and treatment of genetic diseases are outside the scope of Article 16-4. Thus, under French law, cloning technology could legally be used for pre-implantation diagnosis of an existing embryo.[214]

However, Article L. 152-8 of the *Code de la Santé Publique* prohibits *in vitro* conception of human embryos for the purpose of study, research, or experiments and thus would prohibit other research uses of human clones.[215] In addition, Article 511-18 of the *Code Pénal* permits a fine of 700,000 French Francs and seven years of imprisonment for scientists who use embryos conceived *in vitro* for research purposes. Because French law defines an

209. *See id.* at 2 (quoting Article 16-4).
210. *See id.*
211. *See id.*
212. *Id.*
213. *Id.*
214. *See id.* at 4.
215. *See id.*

embryo broadly, these provisions would certainly preclude research on any individual, however conceived, who could potentially be implanted and carried to term.[216]

Additional legal obstacles to human cloning are found in Articles L. 152-1 through 152-3 of the *Code de la Santé Publique.* Article 152-2 restricts the use of assisted reproductive technologies to those which further of a couple's parental project. Even in this context, however, Article 152-3 limits the means that a couple may employ when such a project is to take place outside the natural process to "medically assisted procreation," defined in Article 152-1 as "clinical and biological practices allowing [*in vitro*] conception, embryo transfer, and artificial insemination, as well as any technique with equivalent effect."[217] While the listed procedures all serve to remedy patients' infertility by reestablishing the natural process in which gametes are fused, cloning techniques permit reproduction without a new fusion of the gametes.[218] Unless they are considered to have no greater effect in remedying an infertility problem than the other procedures mentioned in Article 152-1, cloning techniques cannot qualify as medically assisted procreation and, under Article 152-3, may not be employed even to further a couple's parental project. Taken as a whole, these articles comprehensively ban human cloning for reproductive purposes.

C. The United Kingdom

Although the French government has strongly opposed human cloning, some members of the Council of Europe have reacted to the prospect more cautiously. The United Kingdom is one of fourteen member nations that has not yet indicated what action it will take with regard to the convention on human rights and biomedicine.[219] Like France, the United Kingdom has enacted no new legislation to respond to the possibility of cloning humans. Rather than broadly interpreting its existing legislation to prohibit all forms of cloning, the United Kingdom has left the issue in the hands of a government agency, the Human Fertilisation and Embryology Authority. This entity was created and remains governed by the Human Fertilisation and Embryology Act of 1990.[220]

This Act empowers the Authority to grant licenses to individuals thereby authorizing them to provide fertility treatment services, the storage of gametes and embryos, or the use of embryos for research activities.[221] Those not

216. *See id.* at 2.
217. *See id.* at 4.
218. *See id.*
219. *See* Dommel & Alexander, *supra* note 192, at 260.
220. *See* Human Fertilisation and Embryology Act, 1990, ch. 37, § 5 (Eng.).
221. *See id.* § 11(1)(a)-(c).

licensed by the Authority are prohibited from creating a human embryo outside the human body and from using embryos for treatment or research purposes.[222] Individuals who violate these provisions are subject to criminal prosecution that could result in a fine and imprisonment of up to two years.[223] Because cloning techniques necessarily result in the creation of a new embryo, the criminal liability provisions of the Act make it unlikely that researchers will employ them without first obtaining a license from the Authority.

Even licensed individuals, however, are unlikely to employ cloning techniques. Under § 25(1), the Authority may promulgate regulations giving guidance about the proper conduct of those acting under a license.[224] Although the Act does not make blastomere separation illegal, the Authority has determined that those holding a license may not use of this technique to create embryos, and thus, blastomere separation has been effectively banned in the United Kingdom.[225] Because the Act expressly states that a license cannot authorize conduct proscribed by the Authority's regulations, those who are licensed to perform blastomere separation on an embryo may be punished by a fine and up to ten years of imprisonment.[226]

The Act expressly proscribes nuclear transfer, although the proscription may not apply to the specific method of cloning that produced Dolly the lamb. Section 3(3)(d) prohibits "replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo."[227] This language is unclear whether the prohibition extends to the nuclear transfer used in cloning. In both embryonic and adult cell nuclear transfer, the nucleus transferred is fused with an enucleated egg, not the "nucleus of a cell of an embryo" as described by section 3(3)(d). The definitional sections of the Act confirm this discrepancy, defining an embryo as "a live human embryo where fertilisation is complete" and eggs as "live human gametes . . . not . . . in the process of fertilisation."[228] However, under the Act, eggs in the process of fertilization are treated as embryos.[229] If the process of fertilization begins upon the enucleation of the egg prior to the nuclear transfer, the egg would be treated as an embryo under the Act, and nuclear transfer cloning would be prohibited by section 3(3)(d).

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222. *See id.* § 3(1)(a)-(b).
223. *See id.* § 41(4)(a).
224. *See id.* § 25(1).
225. *See* NABER, *supra* note 7, at 265.
226. *See* Human Fertilisation and Embryology Act, 1990, §§ 3(3)(c), 41(1)(b) (Eng.).
227. *Id.* § 3(3)(d).
228. *See id.* §§ 1(1)(a), 4.
229. *See id.* § 1(1)(b).

Some experts believe that courts will likely interpret the term embryo expansively so as to prohibit nuclear transfer as a method of cloning. For example, one expert has stated, "Legal opinions given to Parliament conclude that should the case arise, an extensive definition of an embryo would be adopted which should cover the Dolly case."[230] However, even if the Act does not prohibit nuclear transfer cloning, the Authority itself may still proscribe the technique pursuant to its authority to regulate proper conduct of licensees. Whether prohibited by the Act or by regulations, the use of nuclear transfer cloning techniques, like the use of blastomere separation, could subject researchers and clinicians to a fine and up to ten years of imprisonment, even with proper licensure.[231]

If the Authority eventually authorizes human cloning, other protections in the Act could be extended to human clones. The Act prohibits the use of an embryo in research after its fourteenth day of development or until the primitive streak appears, whichever is earlier.[232] Presumably, if scientists were allowed to clone embryos pursuant to a license, scientists could only use the cloned embryos for research until expiration of the aforementioned term without becoming subject to the Act's criminal sanctions. As with other prohibited conduct under the Act, research conducted subsequent to the authorized time period, with or without a license, could subject the researcher to a fine and up to ten years of imprisonment.[233]

Section 12(1)(e) of the Act, which prohibits licensees from giving or receiving money or other benefits for a supply of embryos unless authorized by the Authority, may also protect cloned embryos.[234] Licensees who violate this provision are subject to a fine and up to six months imprisonment.[235] While this provision is not limited in application to cloned embryos, clones would certainly fall within the protected class if cloning were allowed. Therefore, under the Act, the Authority's regulations would tightly circumscribe any commodification of cloned embryos.

D. The United States

Compared to France and the United Kingdom, the United States has enacted scant legislation that would restrict the practice of human cloning. Since October 24, 1994, the Fertility Clinic Success Rate and Certification Act of

230. COMITÉ, LEGAL CONSIDERATIONS, *supra* note 196, at 6.
231. *See* Human Fertilisation and Embryology Act, 1990, § 41(1)(b) (Eng.).
232. *See id.* §§ 3(3)(a), (4).
233. *See id.* § 41(1)(b).
234. *See id.* § 12(e).
235. *See id.* § 41(9).

1992 has required all clinics using assisted reproductive techniques that involve the manipulation of human eggs and embryos to report their respective success rates in achieving pregnancies to the Centers for Disease Control and Prevention.[236] This agency is required to publish the information annually for the benefit of consumers.[237] Because all cloning techniques manipulate human eggs and embryos, the use of cloning techniques to assist in fertility treatment would fall within this reporting requirement. At the very least, this Act would provide the federal government with a means of monitoring clinics that engage in such practices and provide the public with information about their treatment of infertility.[238]

The federal government's refusal to fund embryo research also impedes cloning. Congressional appropriations to the Departments of Labor, Education, and Health and Human Services continue to prohibit the federal funding of experiments that would create a human embryo for research purposes or that would knowingly subject a human embryo to risk of injury or death for non-therapeutic research.[239] Because this prohibition is contained in an appropriations bill, it must be renewed annually. The 1998 appropriations bill includes, within the definition of "human embryo," organisms derived by cloning "from one or more human gametes or human diploid cells."[240] Because the cells used in blastomere separation and embryonic nuclear transfer have not yet differentiated into either haploid germ cells or diploid somatic cells, the congressional definition of embryo may exclude the experimental use of these techniques from the prohibition on federal funding. Nevertheless, because all forms of cloning necessarily result in the creation of new individuals capable of being implanted and carried to term, these individuals are likely to be treated as embryos, and the prohibition against federal funding for such research would apply.

However, to ensure this result, President Clinton issued a memorandum in March 1997 to the heads of all executive departments and agencies directing that "no federal funds shall be allocated for the cloning of human beings."[241] The

236. *See* Fertility Clinic Success Rate and Certification Act of 1992 §§ 2(a)(1), 8(1), 42 U.S.C. §§ 263a-1(a)(1), 263a-7(1) (1994).

237. *See id.* § 6(1)(A), 42 U.S.C. § 263a-5(1)(A).

238. *See* NBAC REPORT, *supra* note 1, at 88.

239. *See id.* at 5, 88. *See also* Omnibus Consolidated Appropriations Act, Pub. L. No. 104-208, § 512, 110 Stat. 3009-270 (1996); The Balanced Budget Downpayment Act, I, Pub. L. No. 104-99 § 128, 110 Stat. 34 (1996).

240. Act of Nov. 13, 1997, Pub. L. No. 105-78, § 513(b), 111 Stat. 1467 (1997) (making appropriations for the Departments of Labor, Health and Human Services, and Education and related agencies for the fiscal year ending Sept. 30, 1998).

241. President's Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 33 WEEKLY COMP. PRES. DOC. 281 (1997).

President explained that the directive was necessary because the congressional appropriations restrictions on embryo research did not fully ensure that federal funds would not be used to create human clones. Moreover, the President noted that current restrictions needed to be broadened in order to explicitly ban federal funding of projects that would create human embryos for implantation purposes. Finally, while the congressional restrictions applied only to projects funded by the Departments of Labor, Education, and Health and Human Services, other federal agencies remained free to fund human cloning projects.[242]

Federal regulations governing the use of human beings in research would also protect human clones. Seventeen U.S. government agencies have adopted what has become known as the Common Rule, a policy for the protection of human subjects.[243] The Common Rule, which mirrors U.S. Department of Health and Human Services regulations, requires that Institutional Review Boards (IRB) approve research that involves federal funds and research performed at institutions that have executed a "multiple assurance agreement" with the federal government.[244] These boards, appointed by the institutions they serve, are charged with ensuring that human subjects are not exposed to unreasonably risky experiments. To the extent that federal funding underwrites human cloning experiments or these experiments take place at institutions subject to the Common Rule, any reservations that board members may have about the risk of physical harm to human clones will inhibit the approval required for the experiments to proceed.[245] However, the decentralized IRB system cannot ensure a uniform policy with respect to cloning. Substantial criticism has been directed against the boards, claiming that the boards are inadequate for their tasks due to overwork, conflicts of interest, and the absence of expertise. The inexperience of board members with novel technologies such as human cloning may make it even more difficult for them to enforce human subject protections in cloning research.[246]

Moreover, because institutions voluntarily execute the multiple assurance agreements, IRB protection may not extend to many research projects. Organizations that receive significant support from the U.S. government for research involving human subjects are more likely to agree to subject their non-federally funded research to the Common Rule, than institutions who rely to a greater extent on private funding.[247] One commentator stated, "The net effect

242. *See id.*

243. *See* Dommel & Alexander, *supra* note 192, at 265.

244. *See* Basic HHS Policy for Protection of Human Research Subjects, 45 C.F.R. § 46.109 (1996).

245. *See* NBAC REPORT, *supra* note 1, at 88.

246. *See id.* at 100.

247. *See* Dommel & Alexander, *supra* note 192, at 274.

of these policies is to eliminate virtually all federal funding for research to perfect methods for cloning human beings, as even research aimed at initiating a pregnancy would probably involve creating and destroying many embryos that fail to develop normally."[248] Nevertheless, while withholding federal funding impedes some scientific research at institutions dependent upon federal funding, privately financed research at institutions not subject to the Common Rule have unfettered discretion to conduct scientific research. The restrictions on federal funding which aim to control embryonic research thus limit the federal government's ability both to monitor the state of research and to safeguard its quality.[249] Unless further legislative restrictions are enacted, researchers at privately funded institutions could attempt human cloning without regard for federal protections of human subjects.[250]

At present, Congress is considering various bills that would explicitly ban or restrict human cloning in the United States.[251] One of the early legislative initiatives, the Human Cloning Prohibition Act, was introduced on March 5, 1997, and makes it "unlawful for any person to use a human somatic cell for the process of producing a human clone."[252] By its language, the bill does not apply to techniques that use cells other than human somatic cells for cloning purposes. In both blastomere separation and embryonic nuclear transfer, the cells isolated or transferred would not yet have differentiated into somatic cells. In addition, nuclear transfer would require the use of female eggs, which are germ cells rather than somatic cells. Thus, if enacted, the new law would not restrict cloning by blastomere separation or embryonic nuclear transfer. A violation could result in a civil penalty of up to $5000.[253] However, a civil penalty of only $5000 is not likely to deter researchers from creating a clone by somatic cell nuclear transfer. Given the apparent willingness of many couples to pay even large sums for assisted reproductive services, an additional $5000 charge might not be substantial enough to deter individuals who believe they need these services. If true, this charge may be passed on to customers as a cost of doing business.

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248. NBAC REPORT, *supra* note 1, at 89.

249. *See Technological Advances in Genetics Testing: Implications for the Future*, 104th Cong. 84 (1996) (statement of Karen H. Rothenberg, Professor of Law and Director, Law and Health Care Program, Univ. of Md. Sch. of Law).

250. *See Scientific Discoveries*, *supra* note 29, at 40 (statement of R. Alta Charo, Member, Nat'l Bioethics Advisory Comm'n and Assoc. Professor of Law and Med. Ethics, Univ. of Wis.).

251. *See* H.R. 923, 105th Cong. (1997).

252. *Id.* § 2(a).

253. *See id.* § 2(b).

In June 1997, President Clinton transmitted to Congress a proposal for legislation banning human cloning.[254] This proposal, the Cloning Prohibition Act of 1997, has been considered alongside congressional legislation by both House[255] and Senate committees.[256] If enacted, this bill would introduce a five-year legislative ban on the use of somatic cell nuclear transfer to produce human children. Violators of the ban would be subject to substantial, and perhaps draconian, civil penalties.[257] Like the Human Cloning Prohibition Act, the President's bill does not ban the use of other cloning techniques. However, unlike this other bill, the President's bill does not ban the use of cloning for embryonic research.[258] One commentator has stated that the bill implicitly invites researchers to manufacture human embryos as a means of gathering information during the five-year waiting period.[259] Others have criticized the bill's sunset provision, which leaves open the possibility of using cloning to create children in the future.[260]

To complicate matters further, the President's bill bans the use of somatic cell nuclear transfer "with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being."[261] However, the bill's focus on intent is a mistake, because researchers could be prosecuted for intending to use the technique to create a human child, even when no child results. If researchers unintentionally create a child using somatic cell nuclear transfer, they could defend their conduct on the grounds of not having the requisite intent. Thus, as Alison Taunton-Rigby has noted, "[i]f the gravamen of the violation is the *act* of using somatic cell nuclear transfer technology to create a human being, then intent should not be relevant."[262]

In addition to these two bills, other legislation has been introduced that would permanently ban federal funding of cloning research. The Human Cloning Research Prohibition Act, introduced in the U.S. House of

254. *See* President's Message to Congress Transmitting the Proposed "Cloning Prohibition Act of 1997," 33 WEEKLY COMP. PRES. DOC. 845 (1997).

255. *See Banning Federal Funds, supra* note 75 (statement of Alison Taunton-Rigby, President and CEO, Aquila Biopharmaceuticals).

256. *See Ethics and Theology, supra* note 100, at 1 (statement of Sen. Bill Frist).

257. *See Banning Federal Funds, supra* note 75 (statement of Alison Taunton-Rigby, President and CEO, Aquila Biopharmaceuticals).

258. *See Ethics and Theology, supra* note 100, at 42 (statement of Edmund D. Pellegrino, Professor of Med. and Med. Ethics, Georgetown Univ.).

259. *See id.* at 43.

260. *See* American Ass'n for the Advancement of Science, Ctr. for Science & Tech. in Congress, *President's Commission Issues Cloning Recommendations* ¶ 5 (July 1997) <http://www.aaas.org/SPP/DSPP/CSTC/bulletin/articles/7-97/cloning.htm>.

261. *Banning Federal Funds, supra* note 75 (statement of Alison Taunton-Rigby, President and CEO, Aquila Biopharmaceuticals).

262. *Id.* (emphasis added).

Representatives on March 5, 1997, and later amended by the Committee on Science, precludes the use of any federal funds to "conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an embryo."[263] If enacted, this bill would fill in where the President's bill leaves off by prohibiting the use of somatic cell nuclear transfer in embryonic research. However, because the bill applies only to publicly funded research, its only real effect would be to make permanent the current ban enacted annually through Congress' fiscal appropriations. Moreover, the bill would not regulate forms of embryo research that derive subjects from other cloning techniques.

An analogous Senate bill was introduced on February 27, 1997. Like its House counterpart, it prohibits the expenditure of federal funds "for research with respect to the cloning of a human individual."[264] This bill defines 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."[265] Although not expressly stated, the bill appears to be designed to ban all research involving embryonic or somatic cell nuclear cloning. Nevertheless, its sweeping language would deter federally funded researchers from undertaking research designed to investigate or develop this technology, even when such research does not involve the creation of an embryo. Therefore, unlike its counterpart in the House, the Senate bill may impose greater restrictions upon federally funded research than current legal obstacles to human cloning research.

The difficulty of defining the scope of proscribed activities without impinging on beneficial uses of cloning technology undermines all of these bills. As the NBAC has noted, "It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science."[266] Those attempting to regulate human cloning appear to be experiencing exceeding difficulty in drafting precise but not overbroad terms, thus creating a substantial risk that any enacted law could ban beneficial research and delay the development of new diagnostic tests and therapies.[267] A representative of the Biotechnology Industry Organization explained the problem in detail: "The most serious issue is that . . . [the] pending bills do not use scientifically accurate terms, even of such key terms as

263. H.R. REP. NO. 105-239, § 2 (1997).

264. S. 368, 105th Cong. § 1(a) (1997).

265. *Id.* § 1(b).

266. NBAC REPORT, *supra* note 1, at 102.

267. *See Banning Federal Funds, supra* note 75 (statement of Alison Taunton-Rigby, President and CEO, Aquila Biopharmaceuticals).

'somatic cell nuclear transfer.'"[268] Any bill that prohibits the "process" of producing a human clone through somatic cell nuclear transfer may be too broad, thus perhaps leading to broad interpretations that would prohibit all research that is part of this process, even when no clone results. Such indeterminacy of application and imprecise or inadequate definitions permit a wide range of interpretation as to the scope of the proposed legislation.[269]

VI. CONCLUSION

Recent advances in reproductive technology have made it possible for scientists to clone human beings, for the first time in human history. Cloning promises agricultural and medical advances that could enhance species diversity, improve the food supply, provide new pharmaceuticals, eliminate the shortage of transplant organs, and provide new cures for many diseases. Cloning could also further human reproductive goals, thus benefiting infertile couples as well as those undergoing IVF and circumventing genetically inherited diseases in children otherwise at risk.

Unlike France and the United Kingdom, however, the United States does not presently have legislation in place that would directly regulate human cloning. Precisely defining terms, however, has been complicated by the lack of consensus among scientists as to the meaning of key concepts and terms,[270] and a great danger exists that imprecise drafting or failure to use appropriate terms of art will not communicate effectively to scientists. Uncertainty about the bounds of proscribed conduct, together with the threat provided by statutory sanctions, will make any statute enacted particularly likely to chill a broad range of research not properly subject to a ban.[271] In devising a regulatory scheme, therefore, Congress must exercise caution to avoid overly broad legislation that would either violate fundamental rights protected by the Constitution or preclude beneficial uses of cloning technology.

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268. *Id.*
269. *See id.*
270. *See id.*
271. *See id.*