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International convention against the reproductive cloning of human beings

Considerations of the Holy See on human cloning

In view of the debate at the General Assembly of the United Nations on an international convention against the reproductive cloning of human beings

1. The Holy See is convinced of the need to support and promote scientific research for the benefit of humanity. Thus, the Holy See earnestly encourages investigations that are being carried out in the fields of medicine and biology, with the goal of curing diseases and of improving the quality of life of all, provided that they are respectful of the dignity of the human being. This respect demands that any research that is inconsistent with the dignity of the human being is morally excluded.

2. There are two potential sources of stem cells for human research, firstly "adult" stem cells, which are derived from the umbilical cord blood, the bone marrow and other tissues, and secondly "embryonic" stem cells, which are obtained by the disaggregation of human embryos. The Holy See opposes the cloning of human embryos for the purpose of destroying them in order to harvest their stem cells, even for a noble purpose, because it is inconsistent with the ground and motive of human biomedical research, that is, respect for the dignity of human beings. However, the Holy See applauds and encourages research using adult stem cells, because it is completely compatible with respect for the dignity of human beings. The unexpected plasticity of adult stem cells has made it possible to use this type of undifferentiated, self-renewing cell successfully for the healing of various human tissues and organs,[1] particularly in hearts damaged after myocardial

[1] Korbling M., Estrov Z., "Adult Stem Cells for Tissue Repair — A New Therapeutic Concept?", *New England Journal of Medicine*, 2003, vol. 349. Bunting K., Hawley R., "Integrative molecular and developmental biology of adult stem cells", *Biology of the Cell*, vol. 95 (2003). Wang J., Kimura T., Asada R., Harada S., Yokota S., Kawamoto Y., Fujimura Y., Tsuji T., Ikehara S., Sonoda Y., "SCID — repopulating cell activity of human cord blood-derived CD34-cells assured by intra-bone marrow injection", *Blood*, 2003, vol. 101 (8). Gluckman E., Broxmeyer H. E., Auerbach A. D. et al., "Hematopoietic reconstitution in a patient with Fanconi's anemia by means of umbilical-cord blood from an HLA-identical sibling", *New England Journal of Medicine*, 1989, vol. 321.

infarction.[2] The multiple therapeutic achievements that have been demonstrated using adult stem cells, and the promise they hold for other diseases, such as neurodegenerative disorders or diabetes, make efforts to support this fruitful avenue of investigation an urgent matter.[3] Above all, it is universally agreed that the use of adult stem cells does not entail any ethical problems.

3. By contrast, research using human embryonic stem cells has been hampered by important technical difficulties.[4] Embryonic stem cell experiments have not yet produced a single unqualified therapeutic success, not even in animal models.[5] Moreover, embryonic stem cells have caused tumours in animal models[6] and might seed cancer if administered to human patients.[7] Unless these grave hazards are removed, embryonic stem cell experiments will not have any clinical application.[8] Technical problems aside, the need to extract these cells from living human embryos raises ethical questions of the highest order.

4. The so-called "therapeutic cloning", which would be better called "research cloning" because we are still far from therapeutic applications, has been proposed in order to avert the potential immune rejection of embryonic stem cells derived from a

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[2] Wollert K. C., Meyer G. P., Lotz J., Ringes-Lichtenberg S., Lippolt P., Breidenbach C., Fichtner S. Korte T., Hornig B., Messinger D., Arseniev L., Hertenstein B., Ganser A., Drexler H., "Intracoronary autologous bone-marrow cell transfer after myocardial infarction: the BOOST randomised controlled clinical trial", *Lancet*, 2004, Vol. 364, Issue 9429. Beltrami, A. P., Barlucchi, L., Torella D., Baker M., Limana F., Chimenti S., Kasahara H., Rota M., Musso E., Urbanek K., Leri A., Kajstura J., Nadal-Ginard B., Anversa P., "Adult cardiac stem cells are multipotent and support myocardial regeneration" *Cell*, 2003, Vol. 114 (6). Stamm C.,Westphal B., Kleine HD., Petzsch M., Kittner C., Klinge H., Schumichen C., Nienaber CA., Freund M., Steinhoff G., "Autologous bone-marrow stem-cell transplantation for myocardial regeneration" *Lancet*, Vol. 361, Issue 9351.

[3] See: Mezey E., Key S., Vogelsang G., Szalayova I., Lange G. D., Crain B., "Transplanted bone marrow generates new neurons in human brains", *Proceedings of the National Academy of Sciences of the United States of America,* 2003, Vol. 100 (13*).* Vescovi AL., Martino G., "Injection of adult neurospheres induces recovery in a chronic model of multiple sclerosis" *Nature*, 2003, Vol. 422 (6933). Hess D., Li L., Martin M., Sakano S., Hill D., Strutt B., Thyssen S., Gray D. A., Bhatia M., "Bone marrow-derived stem cells initiate pancreatic regeneration", *Nature Biotechnology*, 2003, Vol. 21 (7). Horb M. E., Shen C. N., Tosh D., Slack J. M., "Experimental conversion of liver to pancreas", *Current Biology*, 2003, vol. 13 (2).

[4] See Stojkovic M., Lako M., Strachan T., Murdoch1 A., "Derivation, growth and applications of human embryonic stem cells", *Reproduction,* 2004, Vol. 128.

[5] Freed C. R., "Will embryonic stem cells be a useful source of dopamine neurons for transplant into patients with Parkinson's disease", *Proceedings of the National Academy of Sciences of the United States of America,* 2002, Vol. 99 (4).

[6] Tsai R. Y., McKay R. D., "A nucleolar mechanism controlling cell proliferation in stem cells and cancer cells", *Genes and Development*, 2002, Vol. 16 (23). Wakitani S., Takaoka K., Hattori T., Miyazawa N., Iwanaga T., Takeda S., Watanabe TK., Tanigami A., "Embryonic stem cells injected into the mouse knee joint form teratomas and subsequently destroy the joint", *Rheumatology*, 2003. Vol. 42. Erdö F., Bührle C., Blunk J., Hoehn M., Xia Y., Fleischmann B., Föcking M., Küstermann E., Kolossov E., Hescheler J., Hossmann K.A., Trapp T., "Host-dependent tumorigenesis of embryonic stem cell transplantation in experimental stroke", *Journal of Cerebral Blood Flow and Metabolism*, 2003, Vol. 23 (7).

[7] Marx J., "Mutant stem cells may seed cancer", *Science*, Vol. 301 (5638).

[8] The fact that these epigenetic factors that contribute to the development of embryonic stem cells in the embryo are also the ones that contribute to the development of cancers in the adult is troubling. In fact, stem cells have been found in tumours. Normile D., "Cell proliferation: Common Control for Cancer, Stem Cells", *Science*, 2002, Vol. 298. Valk-Lingbeek M. E., Bruggeman S. W., Van Lohuizen M., "Stem cells and cancer: the polycomb connection", *Cell*, 2004, Vol. 118, Issue 4.

donor other than the host. However, the use of cloned embryonic stem cells entails a high risk of introducing cells from abnormal embryos into patients. It has been well established that most of the non-human embryos produced through nuclear transfer cloning are abnormal, with a deficiency in several of the genes (imprinted and non-imprinted) necessary to the development of the early embryo.[9] Embryonic stem cells harvested from abnormal and unfit embryos will carry their "epigenetic defects" and transmit at least part of them to their daughter cells. The transfer of such cloned embryonic stem cells into a patient would be therefore extremely hazardous: these cells might provoke genetic disorders, or initiate leukaemias or other cancers. Moreover, a non-human primate model of cloning, which would be necessary in order to conduct experiments to establish safety before attempting therapeutic experiments in human beings, has yet to be developed.[10]

5. The health benefits of therapeutic cloning are hypothetical, inasmuch as the method itself remains mainly a hypothesis. Thus the crescendo of hyperboles extolling the promise of this type of research might in the end undermine the very cause it pretends to serve.[11] Indeed, even putting aside fundamental ethical considerations other than the patient's expectations, the present state of "therapeutic cloning" precludes, now and in the near future, any clinical application.

6. Scientists, philosophers, politicians and humanists agree on the need for an international ban on reproductive cloning. From a biological standpoint, bringing cloned human embryos to birth would be dangerous for the human species. This asexual form of reproduction would bypass the usual "shuffling" of genes that makes every individual unique in his/her genome and would arbitrarily fix the genotype in one particular configuration,[12] with predictable negative genetic consequences for the human gene pool. It would also be prohibitively dangerous for the individual clone.[13] From an anthropological standpoint, most people recognize that cloning is offensive to human dignity. Cloning would, indeed, bring a person to life, but through a laboratory manipulation in the order of pure zootechnology. This person would enter the world as a "copy" (even if only a biological copy) of another being. While ontologically unique and worthy of respect, the manner in which a cloned human being has been brought into the world would mark that person more

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[9] Bortvin A., Eggan K., Skaletsky H., Akutsu H., Berry D. L., Yanagimachi R., Page D. C., Jaenisch R., "Incomplete reactivation of Oct4-related genes in mouse embryos cloned from somatic nuclei", *Development*, 2003, Vol. 130. Mann M. R., Chung Y. G., Nolen L. D., Verona R. I., Latham K. E., Bartolomei M. S., "Disruption of imprinted gene methylation and expression in cloned preimplantation stage mouse embryos", *Biology of Reproduction*, 2003, Vol. 10. Boiani M., Eckardt S., Leu N. A., Scholer H. R., McLaughlin K. J., "Pluripotency deficit in clones overcome by clone-clone aggregation: epigenetic complementation?", *The EMBO Journal*, 2003, Vol. 22 (19). Fulka J., Miyashita N., Nagai T., Ogura A., "Do cloned mammals skip a reprogramming step?", "*Nature Biotechnology*, 2004, Vol. 22 (1). Mann M. R., Lee S. S., Doherty A. S., Verona R. I., Nolen L. D., Schultz R. M., Bartolomei M. S., "Selective loss of imprinting in the placenta following preimplantation development in culture," *Development*, 2004, Vol. 131.

[10] Simerly C., Dominko T., Navara C., Payne C., Capuano S., Gosman G., Chong K.Y., Takahashi D., Chace C., Compton D., Hewitson L., Schatten G., "Molecular correlates of primate nuclear transfer failures", *Science*, 2003, Vol. 300. Wolf D. P., "An opinion on human reproductive cloning", *Journal of Assisted Reproduction and Genetics*, 2001, Vol. 18.

[11] Knight J., "Biologists fear cloning hype will undermine stem-cell research", *Nature*, 2004, Vol. 430.

[12] During the meiotic phase, there is a segregation of alleles with subsequent random assortment of homologues. This "shuffling" of genes, which is the basis for genetic identity, prevents the occurrence of severe genetic abnormalities. There is no such healthy "shuffling" of genes in nuclear transfer cloning.

[13] Healy D. L., Weston G., Pera M. F., Rombauts L., Trounson A. O., "Human cloning", *Human Fertility*, 2002, Vol. 5.

as an artifact rather than a fellow human being, a replacement rather than a unique individual, an instrument of someone else's will rather than an end in himself or herself, a replaceable consumer commodity rather than an unrepeatable event in human history. Thus, disrespect for the dignity of the human person is inherent in cloning.

7. However, some would like to leave the prospect of "therapeutic cloning" out of this proposed international prohibition, as if it were a process different from the reproductive one. The truth is reproductive cloning and "therapeutic" or "research" cloning are not two different kinds of cloning: they involve the same technical cloning process and differ only in the goals being sought. With reproductive cloning, one aims to implant the cloned embryo in the uterus of a surrogate mother in order to "produce" a child; with "research" cloning, one aims to utilize immediately the cloned embryo, without allowing it to develop, thus eliminating it in the process. One can even affirm that any type of cloning is "reproductive" in its first stage, because it has to produce, through the cloning process, an individual autonomous new organism, endowed with a specific and unique identity, before attempting any other operation with that embryo.

8. "Therapeutic cloning" is not ethically neutral. Indeed, ethically speaking, it would even be worse than the "reproductive cloning." In "reproductive" cloning, one at least gives the newly produced human being, innocent of his/her origin, a chance to develop and be born. In "therapeutic" cloning, one uses the newly produced human being as mere laboratory material. Such instrumental use of a human being gravely offends human dignity and humankind. The term "dignity", as used in this position paper and in the Charter of the United Nations, does not refer to a concept of worth based on the skills and powers of individuals and the value that others may attribute to them, a value one might call "attributed dignity", The notion of attributed dignity allows for hierarchical, unequal, arbitrary and even discriminatory judgements. Dignity is used here to mean the intrinsic worth that is commonly and equally shared by all human beings, whatever their social, intellectual or physical conditions may be. It is this dignity that obliges all of us to respect every human being, whatever his or her condition, all the more if he or she is in need of protection or care. Dignity is the basis of all human rights. We are bound to respect the rights of others because we first recognize their dignity.

9. Honesty suggests that if one specific course of research has already demonstrated conditions for success and raises no ethical questions, it should be pursued before embarking on another that has shown little prospect of success and raises ethical concerns. Resources in biological investigations are limited. "Therapeutic cloning" is an unproven theory that may well turn out to be a dramatic waste of time and money. Good sense and the need for goal-oriented, serious basic research therefore calls on the world's biomedical community to allocate the necessary funding to research using "adult" stem cells.

10. The world cannot take two different roads: the road of those who are willing to sacrifice or commercialize human beings for the sake of a privileged few, and the road of those who cannot accept this abuse. For its own sake, humanity needs a common basis, a common understanding of humanity and a common understanding of the fundamental bases upon which all our ideas about human rights depend. It is incumbent upon the United Nations to exert every effort in the search for this basis so that human beings may be respected as they are. To bring forward the project for an international, global prohibition of human cloning is part of the mission and duty of the United Nations.

The Vatican, 27 September 2004