MINISTRY OF SOCIAL AFFAIRS AND HEALTH
The National Advisory Board on Health Care Ethics (ETENE)
Ritva Halila

OPINION

Dnro 13/710/2003

28 August 2003

Ministry of Trade and Industry
Technology Department
P.O.Box 32
FIN-00023 Valtioneuvosto

Ref. Dno. 13/710/2003

Subject **REQUEST FOR AN OPINION CONCERNING THE PROPOSAL BY THE EUROPEAN COMMISSION ABOUT ADDITIONAL INSTRUCTIONS REGARDING THE ALLOCATION OF FUNDS FROM THE SIXTH RESEARCH FRAMEWORK PROGRAMME TO RESEARCH PROJECTS USING STEM CELLS FROM HUMAN EMBRYOS (COM (2003) 390 FINAL)**

The Ministry of Trade and Industry has requested an opinion from the National Advisory Board on Health Care Ethics (ETENE) to enable it to prepare Finland's position regarding the proposal by the Commission concerning implementation regulations for the use of stem cells from human embryos in the European Union's sixth framework programme. As ETENE did not hold a meeting within the time limit, the statement has been prepared by the Chairman and the Secretary General of ETENE. If, at its meeting of 17 September 2003, the Advisory Board wishes to address issues other than those mentioned here, we shall inform you about it later.

Stem cells are cells that are able either a) to multiply without any limit, or b) to transform into other types of cell. Some stem cells can transform into almost any kind of cell, while others, including stem cells present in the skin, can only form one kind of cell tissue. Fertilised egg cells, from which an entire individual is eventually formed, are the earliest and most versatile stem cells. Stem cells that have the ability to transform into any cell type can be isolated from embryos, but in a culture it is no longer possible to grow an entire embryo from them. Stem cells can be found in various foetal tissues. Even in adults, stem cells have been found in many tissues and organs, primarily in tissues that are rapidly renewed. However, even the brain, for example, is known to contain stem cells that the body uses to repair tissue damage. Bone marrow contains a large number of stem cells of the blood cells. These can be collected and used parallel with bone marrow transplantation in the treatment of various cancers and severe haematological diseases.

Stem cells are currently used to a limited extent to repair damage to tissues and organs. In clinical practice, stem cells are currently being used in skin transplantation as well as in the treatment of cancers and haematological diseases. Animal studies have indicated that stem cells can be used to treat diabetes caused by insulin deficiency as well as some neurological diseases, such as parkinsonism and multiple sclerosis, the symptoms of which are caused by tissue destruction. It has also been proposed that stem cells could be used to repair myocardial defects due to causes such as myocardial infarction.

Postal address: P.O.Box 33, FIN-00023 Government
Street address: Kirkkokatu 14 Helsinki, FINLAND
Tel: +358-9-160 01
Direct tel: +358-9-160 73834
Fax: +358-9-160 74312
E-mail: ritva.halila@stm.vn.fi
Internet: www.etene.org

Research on human stem cells is medical research, and in Finland is regulated by the Medical Research Act (488/1999, later the Research Act) and the Act on the Medical Use of Human Organs and Tissues (101/2001, later the Tissue Act). The Tissue Act stipulates that human embryos can only be used for fertilisation treatment and medical research. The Research Act stipulates the conditions under which embryonic research can be conducted. Embryos cannot be produced for research purposes alone, and therefore embryonic research uses only excess embryos from fertilisation treatments or embryos from fertilisation treatment that would otherwise be disposed of for other reasons. The informed consent of the gamete donor is required for embryonic research, and written approval from an ethics committee is required before such a study can begin. In addition, research centres conducting embryonic research need permission from the National Authority for Medicolegal Affairs for their work.

In Finland, human stem cells of embryonic origin are currently prepared and studied at only one study centre, namely the Family Federation of Finland. Stem cell studies have utilised excess embryos, and after the expiry of the storage period the gamete donors have been contacted and their consent requested and received for this. In this sense, the regulation stipulating that only embryos prepared before 27 June 2002 may be used for stem cell research neither changes nor complicates current research in Finland. However, thought should be given to whether such dates are artificial and whether some dates are used to create additional restrictions that do not improve the right of self-determination of individuals as such, or the moral status of foetuses or embryos, from what could not otherwise be achieved by national legislation.

The Commission is not proposing the approval of research aimed at so-called therapeutic cloning. Therapeutic cloning is currently the subject of intensive discussion worldwide. In therapeutic cloning, stem cells are produced from an egg cell and a somatic cell, the nucleus of which is transplanted into the egg cell. Such modified cells function in animal models like fertilised egg cells and start to divide in cell cultures. In therapeutic cloning, stem cells with the same genotype as the donor of the somatic cell can be isolated from such “embryos”.

The Commission justifies its decisions by referring to the statement of the European Group of Ethics (EGE), No. 15, in which the EGE emphasises national legislation and the control of stem cell research. In its statement, the EGE does not prohibit therapeutic cloning as such but says that at the time of preparing the statement, studies on nucleic transfer techniques are premature. In its statement, the EGE also stresses that research on stem cells from other sources, such as excess embryos, foetuses and adult tissues, should be supported. The EGE also emphasises that the research must not cause unnecessary stress or constitute a hazard to women donating the egg cells.

For the other parts, the EGE recommendations such as informed consent, risk/benefit analysis, protection of study subjects, and other recommendations associated with therapeutic purposes have already been covered in our national legislation (the Research Act, the Tissue Act). The questions concerning cell banks are currently under discussion in Finland.

Martti Lindqvist
Chairman

Ritva Halila
Secretary General