NATIONAL COUNCIL OF ETHICS FOR LIFE SCIENCES
Presidency of the Council of Ministers

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OPINION OF THE NATIONAL COUNCIL OF ETHICS FOR LIFE SCIENCES

OPINION ON DRAFT BILLS Nº 126/X (which establishes the Principles of Scientific Research in Stem Cells and the Use in Embryos), and Nº 376/X (which establishes the Legal System for the Use of Stem Cells, for Research Purposes and the Therapeutic Applications)

(July, 2007)

The development of this opinion was in response to the request that the Health Committee of the Assembly of the Republic addressed to the CNECV for an opinion on Draft Bills Nº 126/X (which establishes the Principles of Scientific Research in Stem Cells and the Use in Embryos) and Nº 376/X (which establishes the Legal System for the Use of Stem Cells, for Research Purposes and the Therapeutic Applications).

This opinion is therefore based on the exclusive analysis of the draft bills rather than a deep reflection on stem cell research, as the latter was not requested, and the CNEVC has already given its views in a previous opinion (Opinion on Stem Cell Research – 47/ CNECV/05) which it is remitted to.

In the present opinion each Draft Bill is analysed separately, but the conclusions about each one may, because of the principles they reflect, be applied, autonomously, in a legal text when the final assessment of the bills is made.

I. Analysis of the Draft Bill of the *Bloco de Esquerda* (Left-wing bloc)

Draft Bill n.º 126/X

Objectives of the Bill:

To establish the principles of stem cell research and the use of embryos.

Which principles does it establish for this research?

a) The principle of authorisation by a competent regulating body.

b) The principle of having as its objective the prevention, diagnosis or treatment of human diseases or the perfection of medical techniques and knowledge;

c) The principle that these objectives can not be achieved by other means;

d) The principle of using unviable embryos;

e) The principle of using supernumerary non criopreserved embryos as they do not present morphological viability criteria;

f) The principle of using criopreserved embyos which are over three years old and which have no parental project;

g) The principle of prohibiting the intentional production of embryos specifically for research purposes;

h) The principle of prohibiting any form of commercialisation;

i) The principle of the creation of a Portuguese Embryonic Stem Cell Bank;

j) The principle of creating a committee to issue opinions on research projects in this area and to accompany the execution of those that are approved.

In order to frame these principles within a legal context, this Draft Bill formulates twelve articles of which Articles 1º, 11º and 12º are merely descriptive.

1. In the light of the previous opinions of this Council, it can be stated that the Principles identified in this Draft Bill have, for the most part, already been received favourably by the CNECV.

Even the Principle identified here in the Project in question as paragraph f) is contemplated in point 12 of Opinion n.º 47/CNECV/2005, which considers that " the harvesting of embryonic stem cells which does not, in itself, cause the destruction of those embryos, does not raise ethical objections. The potential benefit for humanity of the information which may result from scientific research justifies the use of stem cells obtained from cryopreserved embryos for motives unconnected with the harvesting of the stem cells."

This position was approved by the majority and the conflicting views are expressed and justified in the declarations of the members of the Council in the annex to the Opinion.

2. The proposal in Article 3 to set up a Committee for Medical Scientific Research on Human Embryos – the CIMCEH – has given rise to certain ethical reservations because it duplicates responsibilities which have already been attributed, in Chapter VI of Law nº. 32/2006 of 26th July (which regulates the use of medically assisted procreation), to the National Committee of Medically Assisted Procreation.

3. The proposal for the creation of a Portuguese Embryonic Stem Cell Bank, stated in Article 8, even with the referral to Article 19 of Law nº 12/2005 of 26th January (Genetic information and health information) is most unsatisfactory at the ethical level. The capacity to authorise the creation of banks of stem cells is attributed to the CNPMA (Article 30, paragraph e) of Law nº 32/2006 of 26th July).

4. Article 6, "Consent", does not comply with the minimum ethical criteria for the regulation on obtaining consent, even in less sensitive matters than this. It should therefore be totally reformulated and should at least include the provision in Article 19 of Law nº 12/2005 of 26th January, which has not yet been regulated. Point 5 of this Article states specifically "5 – Written informed consent is necessary to obtain and use material for a biological products bank, and the consent form should include information about the purpose of the bank, the entity responsible for it, the types of research to be developed, the potential risks and benefits, the conditions and duration of the storage, the measures taken to guarantee the privacy and confidentiality of the persons participating and the provision for the possibility of communicating or not the results obtained with that material".

In Article 19, which has nineteen items, all of the ethical requirements to be respected in DNA and other biological product banks are clearly stipulated.

However, the fact that law nº 12/2005 of 26th January has not yet been regulated, which it is hoped will treat fully and in detail the question of the information for consent on the part of the couple with the "guardianship" of the embryos to be used, means that it would be inappropriate to provide a fuller commentary on Article 6.

5. Article 7, because, for the use of stem cells, it specifies the provision in Article 9 of Law nº 32/2006 for Medically Assisted Procreation, should mention that this particular research shall be subject to the general rules of Law nº 32/2006. Point nº 2 of article 9 of Law nº 32/2006 allows the legality of scientific research on embryos and the legality of the "constitution of banks of stem cells for transplant programmes or for any other therapeutic purposes".

In conclusion, the principles defined in the Draft Bill are correctly presented. When they are drawn up in the Bill, the aforementioned ethical considerations should be taken into account.

As a whole, Law nº 12/2005 of 26th January and Law nº 32/2006 of 26th July, and particularly their regulations, when they are made, make it unnecessary for a specific law governing scientific research on embryonic stem cells. Furthermore such a specific law could convey to the public the idea that there are no other sources of human stem cells for use in research and in clinical tests.

II. Analysis of the Draft Bill of the Socialist Party

Draft Bill n. º 376/X

1. The preamble of this Proposal refers to Opinion n. º 47/2005 of the CNECV along with other national and international documents, selected from amongst many others because they are in favour of stem cell research. It recognises that Law n. º 32/2006 of 26th July, which regulates the use of medically assisted procreation techniques, has already established a regime for the use of embryos in scientific research but it understands, nonetheless, that still "it is necessary to regulate this sector of scientific research coherently, within an all-encompassing framework – which goes beyond the work with embryonic cells – …"

The objective of this Draft Bill is to "establish the legal regime that the use of stem cells should obey".

2. In fact this Project deals with stem cells of the diverse origins currently known of and which it refers to in n.º 2 of article 2; then in article 5 it refers to Law n.º 32/2006 on issues relating to embryonic stem cells. The remaining articles therefore deal with stem cells which are not obtained from embryos.

3. The ethical question which deserves comment is the question of consent.

In article 4, "General requirements" refers to "The donation of stem cells (…) should always be given expressed and autonomous consent, as the identification data is of a confidential nature, which should be guaranteed by all means".

In article 9, "Consent regime" establishes that "The consent demanded in the terms of articles 6 to 8 (from adult tissue) of this law is presumed when, within an eight day period as from the act which allowed the stem cells in question to be obtained, the donor does not object, in writing, to their use in the terms of and for the effects of this law".

This so-called "anonymous" and presumption-based model of consent is ethically unacceptable in this matter: any norm (ethical or legal) relative to the use of elements of the human body in life always require the free, informed and expressed consent of the donor.

4. Thus the CNECV recommends that article 4 should clearly establish:

a) that the presumed donors be informed, in advance, fully and comprehensively, of the harvesting procedure and the use that will be made of the products harvested, including the possibility of their use for research.

b) that this consent is freely given following the provision of clarifying information and should be expressed in writing.

c) that, with regard to future use, consent may be withdrawn by the donor at any moment, without penalty.

d) that identification data connected with the product harvested can be made semi-anonymous by using codes, and safety rules should be established for the coded file and for accessing the code.

Furthermore,

In the case of blood from the umbilical cord, it is necessary to establish in article 8 that consent for the use of the cryopreserved stem cells expires when the "donor" reaches the age of majority; and the "donor" may revoke consent for the use to be given to the stem cells (particularly in the case of harvesting for public stem cell banks that will be made available for transplants for other immune-compatible receivers).

It is also recommended that article 9 be eliminated, should the conditions for the giving of consent indicated in the first paragraph of this point 4 be favourably received in the Draft Bill.

To end, with reference to n. º 2 of article 2, following paragraph b), a new paragraph should be added, c) amniotic-fluid stem cells.

It is thus recommended, in relation to the principles underlying the research, with the specific characteristics applicable to the object of research (biological material, stem cells, etc.) that there be uniformity and coherence in their application, in keeping with the international norms in effect and with the underlying principles of existing national norms.

Lisbon, 10th July, 2007

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The Opinion was drawn up by the Council member Daniel Serrão.

This opinion was approved in the plenary session on the 10th July, 2007, where the following were present: Paula Martinho da Silva, Agostinho Almeida Santos, António Vaz Carneiro, Daniel Serrão, Fernando Regateiro, João Lobo Antunes, Jorge Soares, Jorge Sequeiros, Maria do Céu Patrão Neves, Maria Fernanda Silva Henriques, Pedro Fevereiro, Marta Mendonça, Miguel Oliveira da Silva, Rui Nunes, Salvador Massano Cardoso.