



Workshop:

Ethical aspects of stem cell repositories and stem cell databases
Brussels, 17 February 2005

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Stem cell research raises a serious political question, discussed in the European Parliament and in the European Commission. The most difficult question is the one of embryonic stem cell research, debated very much at both the EU and the UN level. At the EU level, it is the competence of each member state to regulate the embryonic stem cell research. The EU has no legal competence to regulate it inside the member states. It must respect the law in each member state: no research forbidden in any member state will be supported by Community funds to a legal entity established in that state. However, the EU has the responsibility to implement the EU Framework Programmes and set up clear rules for community funded research raising ethical issues.

In the previous Framework Programmes, FP4 and FP5, the position regarding embryonic stem cell research was not very clear since both Framework Programmes did not exclude embryo research as such. Non-somatic gene therapy and reproductive cloning were always excluded from funding, but not embryo research as such: research on human supernumerary embryos was not excluded from funding. For example, in FP5 about 50 research projects (i.e. about 86 million Euro of total EU support) involved at least 1 stem cell research component and more than 90% of these projects involved adult stem cells, very few involved foetal stem cells and only one involved human embryonic stem cells.

In FP6, adopted on 30 September 2002, the political discussion was more open. Three main principles were defined: the prohibition of human reproductive cloning, the prohibition of non-somatic gene therapy and prohibition of creation of human embryos for research purposes and for stem cell procurement (e.g. by means of Somatic Cell Nuclear Transfer). All these three areas are excluded from funding. However, there was no agreement in the EU Council of Ministers regarding research on human embryos and human embryonic stem cells: during the discussion of FP6 the majority was to accept embryonic stem cell banking and research. In the adoption of the FP6 in 2002 some member states changed their political majority, for example Portugal. Therefore it was impossible to have a qualified majority in one direction or in the other and impossible to find a solution in the Council. However, in the Parliament there was a majority, and the EU Parliament passed a positive decision regarding the use of EU funds for research on

supernumerary embryos. In the Council of Ministers the following compromise was reached: only research involving already banked or isolated human stem cells in culture was agreed to be funded. There is no decision at the Council level, despite the positive opinion of the EU Economic and Social Committee and the positive opinion of the EU Parliament, both passed in 2003. The new member states of the EU also have very different opinions regarding embryonic stem cell research therefore there is the same difficulty in the EU to find a qualified majority.

The Commission has a legal obligation to implement FP6 – and it does not exclude research on human embryonic stem cells. In the FP6 there are 25 research projects involving at least one component of stem cell research. More than 90% of these projects deal with adult stem cells. Very few deal with foetal stem cells, and only two projects conduct research on human embryonic stem cells.

As of 1 January 2004, there are guidelines for the use of banked and isolated human embryonic stem cells in culture, and the evaluation of research proposals is carried out on a case by case and careful analysis basis. There is also a requirement that in order to conduct research on human embryonic stem cells the approval of the relevant national or local ethics committees is mandatory.