Federation of the European Academies of Medicine (FEAM)

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REPORT ON THE **STEM CELL** SESSION AT THE CONFERENCE HELD BY FEAM IN ROME ON 22 MAY 2004.

The programme included several presentations on the scientific, legal, bioethical and research aspects regarding the use of embryonic stem cells with possible clinical applications. Speakers of this session were: **Luigi Frati**, Vice-president of FEAM who presented an introduction and overview of the topic; **Giulio Cossu**, Director of the Stem Cell Research Institute/Dibit, Milano who presented scientific examples on the possible use of stem cells for therapy: e.g. the case of muscular dystrophy; **Claude Sureau**, Académie de Médecine de France who illustrated the recent French regulations on stem cell research; **Cinzia Caporale**, Vice-President UNESCO Intergovernmental Bioethics Committee (IGBC) who addressed the question of the bioethics involved in the use of stem cells; and finally **Octavi Quintana Trias**, Director of the Health Directorate European Commission DG Research, who presented the research and legal aspects within the European Union.

Stem cells have become of extreme interest for the possible applications in the cure of several diseases. Stem cells are defined as a compartment of cells that maintain throughout life the ability of self-renewal, are not committed to any specific cell type but can at any moment differentiate in one or more specialized cell type. Stem cells may easily be obtained from embryonic tissues and more recently several reports have shown that also adult tissues maintain a stem cell population (*adult stem cell population*) with similar features.

The use of embryonic stem cells has in the past been prohibited because of ethical concerns (Oviedo regulation of 1997) and this agreement has been enforced in several countries (most of European countries). The possibility of employing human embryonic stem cell lines has been explored mostly by US and UK laboratories. These cell lines, that have been made available to researchers, present problems since chromosomal abnormalities have been demonstrated and the possible risk of tumors needs to be addressed.

In adult tissues, the main problem and the scientific debate has been in regard to difficulties encountered in defining the actual ¨*true stem cell*¨ within adult tissues. Moreover the issue as to whether adult stem cells are indeed present in all fully differentiated tissues and are responsible for improved tissue function (for example: heart infarction) after differentiation into fully mature phenotype cells, or transdifferentiation after cell fusion with local adult cells, is at the moment still under investigation.

The research road map that would provide the ultimate rationale for the clinical use of progenitor/stem cells includes:

- Demonstration that stem cells differentiate into fully mature cells in the absence of cell fusion
- Documentation that cells can function as progenitors in adult tissues and that improvement of tissue/organ function is associated with newly differentiated cells
- The identification of significant molecular markers to characterize subsets of stem cells
- Translation of the experimental results from mice to large animals reflecting human physiology

The ethical/legal issues affect mostly the possible use of embryonic stem cells as well as the use of nuclear transfer methodology. The main points of this debate are:

1. The use of supernumary embryos, embryos from abortions, non-viable embryos, established embryonic cell lines
2. The individual nuclear transfer methodology for the generation of embryonic stem cells
3. Variation in religious views among different countries
4. Patents by institutions/companies/scientists
5. Consent by donors and transfer agreements for exchange of cells (international guidelines)
6. Funding of research on human embryos and embryonic stem cells (EC 6th Framework will proceed on a case by case analysis after approval by relevant national/local ethical committees)

FEAM proposes the following conclusions:

- A general consensus exists among the Academies supporting the use of embryonic stem cells (from supernumary embryos or from abortion and from non-viable embryos) as well as the use of the nuclear transfer methodology for research purposes only.
- The use of the above material should be strictly controlled by competent authorities (Special committees as proposed in France and Spain).
- A written consent from parents is mandatory.
- Reproductive cloning and the creation of embryos for research/commercial/industrial purposes are to be strictly forbidden.

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