20 ARGUMENTS FOR MAKING <u>FUNDING OF ALTERNATIVE STEM CELLS</u> AN EU RESEARCH POLICY PRIORITY AS AGAINST EU FUNDING OF RESEARCH USING HUMAN EMBRYONIC STEM CELLS

I - POLITICAL AND LEGAL ARGUMENTS (in particular, with regard to Member States)

1. Lack of consensus. Funding of research using hESC is controversial; conversely, funding research on alternative stem cells, because they enjoy wide acceptance – both on scientific and ethical grounds – is broadly consensual among Member States.

2. Discrimination based on national ethical options. This consensus on alternative stem cell research is reached also because funding such fields of research, unlike research using hESC, does not raise the issue of discriminatory access to EU funding by Member States as a consequence of their legitimate national options regarding the ethical and legal frameworks for research.

3. A tax paradox. Moreover, funding of research using hESC raises a paradox arising from the fact that projects that make use of hESC lines - whose use may be punished as a criminal offense in some Member States - are nevertheless eligible for EU support with common funds to which all Member States contribute, including those very Member States which criminalise such activities.

4. Respect for cultural diversity and for national identity. In contrast, the excluding of research projects using hESC from EU funding does not, in practice, have an automatic effect on the policy options of each Member State with regard to financing this type of research in accord with its national legislation, as is currently the case. Such legislation, and the ethical options underpinning it, should be respected by the EU in conformity with the principles of respect for cultural diversity and for the national identity of member States as enshrined in the Treaties.

5. Respect for subsidiarity. As early as 2005, the EP adopted a Resolution where it had already considered that "EU funding should concentrate on alternatives like somatic stem cell and umbilical cord stem cell research, which are accepted in all Member States and have already led to successful treatment of patients"; moreover, with regard to hESC research, the EP called on the Commission to "apply the subsidiarity principle (...) so that Member States in which this kind of research is legal fund it from their national budgets".

6. EU citizens have shown a preference for adult stem cells. One should still take into consideration the evolution of public opinion in Europe: 56% of respondents to a recent Eurobarometer Survey answered positively when asked whether an embryo is a human being immediately after fertilisation; 69% approved the research on adult stem cells whereas fewer Europeans approved embryonic stem cell research.

7. Priority for alternative stem cells to achieve "smart growth". In the light of the above, research on alternative stem cells should be prioritised in the context of EU funding in the new Horizon 2020 programme, with the consequent reallocation of resources. In addition, such areas are more likely to meet the objectives for the realisation of "smart growth" in the light of the 2020 Strategy and within the framework laid down in Article 179 TFEU (and following). These objectives relate to the effectiveness and performance of projects, results-driven funding, actual innovation in the market and impact on society, creating a real European added value, strengthening cross-border collaborative research and the mobility of researchers, the construction of European networks and of the European research area, and the exchange of information and research results.

8. The proposals can be considered as violating the unity of the EU legislative order. The proposals do not take into consideration the recent ruling of the European Court of Justice in the case Greenpeace v. Brüstle. The Court clearly defines the human embryo as a human ovum, as soon as fertilized, or as the product of cloning, and confirms that biotechnological inventions using hESC cannot be patented. If the EU legal order is meant to be consistent and internally coherent, the same criterion that underpins the non-patentability of hESC should also be applied in the field of research funding; consequently, projects covering either research activities which destroy human embryos or any subsequent steps involving hESC obtained in a previous derivation process that entails such destruction, should not be admitted for funding.

9. Risk of the Commission proposals possibly being illegal. Beyond that, however, and following from what has been stated above, proposals allowing EU funding of research with hESC might come to be considered illegal. This thesis has already been defended by distinguished lawyers in their legal advice. It is not reasonable to put at risk a 80-billion-euros programme on crucial funding for numerous fields of research just because of an insistence on a provision which foresees funding whose legality is, to say the least, highly disputable; and that therefore may be judicially declared void.

10. A strictly ideological option. Insistence on funding projects which use hESC and, even more, the shift away from the current practice of not funding destructive research on embryos, including for procurement of hESC, can only be explained in terms of an ideological prejudice, since, as demonstrated throughout this list of

arguments, there is no objective reason, scientific, legal, ethical or other, that can be called on for support of that policy option.

II - SCIENTIFIC ARGUMENTS

11. Scientifically outdated. The Commission, in its Statement in 2006, justified the funding of research using hESC making reference to it as a "promise". However, from the scientific point of view, hESC so far have been rather disappointing, less and less representing clinical promise. It is noteworthy that recently, Geron Corp., the world's leading embryo research company, announced it was closing down its stem cell programme.

12. There are better ethical and clinical alternatives. In contrast, there have been continuing scientific advances in fields of research involving alternative stem cells (adult, derived from umbilical cord or induced pluripotent) which present better prospects for clinical applications; or have indeed already widespread clinical results (and do not raise any special ethical problems).

13. The **2012** *Nobel Prize* physician and genetician laureates John B. Gurdon and Shinya Yamanaka have confirmed through their approach that therapeutic pluripotent cells will soon be made available through alternative processes, avoiding any destruction of human embryos, thus in line with our ethics. The whole scientific community is aware of this.

III - ECONOMIC ARGUMENTS

14. Resource diversion. Funding of projects that use hESC diverts resources from alternative stem cell research, with all its benefits and advantages.

15. Economic inefficiency. A main focus of Horizon 2020 is to help "innovative enterprise to develop their technological breakthroughs into viable products with real commercial potential". However, due to the rule of nonpatentability (see argument 8 above), the potential results of research using hESC are legally prevented from being turned into actual innovation in the market.

IV - ETHICAL ARGUMENTS

16. Human Embryo destruction is ethically unacceptable. Funding research involving the destruction of human embryos, including that for the procurement of hESC, is ethically unacceptable.

17. hESC use is ethically unacceptable. It is therefore equally unacceptable, from the ethical point of view, to fund projects involving hESC in steps subsequent to their derivation; such funding itself stimulates the procurement of hESC and, thus, escalates human embryo-destructive research activities.

18. It is a contradiction to destroy human lives to save the integrity of animals. Moreover, the EU finds itself in a fundamental ethical contradiction: On the one hand, the EU determines a reduction in the use of animals in research and testing – as reflected in recital 24 of the proposal for a Regulation establishing Horizon 2020. On the other hand, the EU promotes the escalating use of human embryos in research and testing, funding projects involving hESC in steps subsequent to their derivation (as reflected, for example, in recital 25 of the same proposal). As a matter of fact, there is indeed a link between both of these results, as alternative (toxicity) testing methods using hESC have been researched with funds provided by the EU in order to advance the eventual replacement of the use of animals for scientific purposes. The use of alternative testing methods using hESC can even be obligatory for Member States in certain circumstances.

19. The new ethical framework proposed is weaker than the current one. Although the new proposals presented by the Commission incorporate - and thus confer on them true legal force - some of the commitments already undertaken by the Commission in its Statement in 2006, they - surprisingly – exclude the most important one: the commitment (§12) that the EU Commission "will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells". This means that the instruments proposed present an ethical framework which is in fact weaker than the one which applies in the current research programme (2007-2013).

20. The danger of a non-ethical hidden agenda becomes ever more clear, given the current unacceptable use of hESC extracted from human embryos, condemned to death by purpose, and the frightening eugenic considerations, such as the double preimplantatory diagnosis, when alternative options have been made available.