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REPORT

on the ethical, legal, economic and social implications of human genetics

Temporary Committee on Human Genetics and Other New Technologies in
Modern Medicine

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*Changes recommended by the European Society of
Human Genetics*

MOTION FOR A RESOLUTION

European Parliament resolution on the ethical, legal, economic and social implications of human genetics

Comments and recommended changes from the European Society of Human Genetics

- Q. whereas there is no difference between cloning for therapeutic purposes and cloning for the purposes of reproduction, and whereas any relaxation of the present ban will lead to pressure for further developments in embryo production and usage, **(This statement cannot be accepted as there is a big difference between reproductive cloning and therapeutic cloning. It is suggested to exclusively refer to the ban of reproductive cloning. Suggested Q. Whereas there is an International Ban on reproductive cloning)**
- R. whereas the European Union has a duty to encourage research in biotechnologies and human genetics; whereas fundamental research must not be left solely to the commercial sector, and whereas the public interest requires strong support for all forms of research likely to increase knowledge of the human being and, in time, to help to devise new therapies; whereas national prohibitions relating to certain types of research must not prevent the European Union as a whole from supporting such research in those countries in which it is lawful ; whereas only research leading to the cloning of human beings **for reproductive purpose** and changes to the germ line should be prohibited, and whereas therapies should be developed only with a view to treating serious diseases and not to improving new human characteristics,

- V. whereas a growing number of laboratories in Europe are offering genetic testing and analysis services; whereas such practices are becoming increasingly more frequent, following a trend that is bound to gather pace; whereas it would be appropriate to analyse the consequences thereof on people's physical and social development; and whereas such predictive testing practices must never be allowed to replace existing preventive policies in the field of public health, **(this last phrase is inappropriate and should be replaced by: and whereas such predictive testing practices must be incorporated into a more general preventive policy and must only be considered as one way among others to establish risk factors,)**
- AA. whereas abuse of genetic testing, in particular pre-natal and pre-implantation diagnoses, gives rise **(change last two words to: is perceived as giving rise)** to the risk of eugenic practices being carried out, and whereas, for that very reason, PID is illegal in several European countries,
- AH. whereas, with regard to the origin of stem cells, a distinction must be made between embryo stem cells and adult stem cells; whereas research on adult stem cells constitutes a promising and ethically acceptable alternative to the use of stem cells from human embryos; and whereas research on adult stem cells must therefore be accorded unconditional priority, **(change last phrase to: whereas research on adult stem cells must therefore be strongly supported)**
- AI. whereas the development of methods which could reduce the health, i.e. physical and psychological, burdens due to in vitro fertilisation (IVF) and reduce, or even prevent, the production of 'supernumerary embryos' must be encouraged, **(all this paragraph should be deleted as it is not relevant to the topic. The number of supernumerary embryos depend on the strategy defined by the clinician and the biologist in charge of the infertility treatment, usually in agreement with the couple. Supernumerary embryos have to be created because at the moment of fertilizing the egg cells it is not possible to know how many of them will be fertilized. In practice, the extra embryos are frozen for the future use of the couple. When the agreed period of freezing is over, the couple has four options: to continue freezing the embryos, to have the embryos destroyed, to donate them to other infertile couples or to donate them for specified research. It is proposed to replace this paragraph by: whereas reduction of the production of 'supernumerary embryos' is a desirable goal and must be encouraged,)**
- AJ. whereas the conditions for the production and collection of stem cells principally jeopardise the integrity of the female body when therapeutic cloning is involved using supernumerary embryos, **(most people cannot agree with this statement which is not based on any reality. It is proposed to delete this paragraph)**
36. Considers, bearing in mind that the number of genes seems far lower than previously thought, that much less importance should be attributed to the idea that genes are the sole or overriding contributory factor in given outcomes, which appear instead to result from complex interaction processes involving genes, proteins, and environment; **(A totally unscientific statement, since the number of genes does not equate to the degree of genetic influence. To be replaced by: Considers, bearing in mind that**

most biological processes result from complex interaction involving genes, their protein products, and the environment;) once the emphasis on predictivity has been removed, the possibility of using genetic data to assess people's prospects should not be permitted, since the decisive relationship with proteins and environment is disregarded, producing distorted or incomplete images of the person in question; takes the view that an individual does, however, have the right to have genetic tests carried out; **(this latter section to be replaced by: the possibility of using genetic data to assess people's prospects should not be permitted unless useful for preventive measures and having been assessed for their true predictive value; takes the view that an individual does, however, have the right to have genetic tests carried out;)**

50. Notes that, pursuant to Article 6(2)(c) of the Directive, 'uses of human embryos for industrial or commercial purposes' is to be considered unpatentable; urges the Commission to clarify, by issuing a guidance document, by amendment of Directive 98/44/EC or by additional legislation, that hybrids, chimera, human stem cell lines or treatments as well medicines, products or procedures derived from or developed by research on embryos created in vitro for any purpose other than bringing about a pregnancy, shall be excluded from patent protection; **(this paragraph is inadequate: the patent issue is a separate one from the issue of which biological material was used to carry on the research. The Article 6(2)(c) of the Directive, 'uses of human embryos for industrial or commercial purposes' targets the production of embryos for marketing purpose. It does not refer to the patentability of inventions derived from research done using stem cell lines. Stem cell lines are no longer embryos. They are cell lines in no way different from any other type of cell line. We propose to to delete this paragraph.)**
56. Maintains that substantial public funding should be made available for the development and use of scientific methods which will help to avoid the production of 'supernumerary' embryos; **(The number of supernumerary embryos depends on the strategy defined by the clinician and the biologist in charge of the infertility treatment, usually in agreement with the couple. There is no need of further research to decrease this number This paragraph should be deleted)** Member States should examine possibilities which would allow for the adoption of 'supernumerary' embryos by infertile couples;
58. Points out that the production of human embryos by nuclear transfer is the basis for reproductive cloning and that, technically, the implantation of embryos in the womb is a very simple procedure; **(This statement is not appropriate. If it is true that, from a technical point of view the two approaches are similar, it is not a reason for not using nuclear transfer if this technique proved to be necessary to obtain cell lines for producing new therapies for severe conditions. We suggest to delete this paragraph)**
60. Reaffirms, therefore, its position that the most effective and credible way of combating human cloning is to exclude the possibility both of therapeutic cloning and of reproductive cloning of human beings; **(This is not right. The best way is to have a Community-wide ban on reproductive cloning of human beings. We suggest to**

delete this paragraph)

61. Welcomes therefore the decision of the US House of Representatives to prohibit the production of human embryos by nuclear transfer and to impose heavy prison sentences on those who defy the ban, and calls on the Senate to endorse this decision as soon as possible; **(This sentence is not useful. There is no agreement on the US position . We suggest to delete this paragraph)**
69. Expresses its unreserved support for work with adult stem cells and notes with interest that such work has, in some fields of research (e.g. into leukaemia, the treatment of cartilage and bone damage and probably also the treatment of coronary disease), already yielded cures for some patients, whilst embryo stem cell research has hitherto resulted in partial cures being found, and only in experiments on animals; **(This is a false statement. The only positive outcomes so far are with embryonic stem cells. We suggest to replace the paragraph by: Expresses its unreserved support for work with adult stem cells.)**
78. Believes therefore, as far as stem cells are concerned, that research projects using adult stem cells should be treated as the priority for Community funding and that research projects using embryonic stem cells should not receive such funding; **(we suggest replacing this paragraph keeping only: Believes therefore, as far as stem cells are concerned, that research projects using adult stem cells should be treated as the priority for Community funding;)**
79. Recommends that no Community funding be granted for research, technological development and demonstration activities involving:
- (a) the creation of human embryos from donated gametes for anything other than reproductive purposes;
 - (b) the creation of human embryos by means of somatic cell nuclear transfer (therapeutic cloning) and the cloning of human beings (reproductive cloning);**(We suggest replacing this paragraph keeping only: the reproductive cloning of human beings)**
 - (c) research activities aimed at modifying the human germ line;
 - (d) intentional artificial creation of human embryos for any purpose other than bringing about a pregnancy;
 - (e) any other forms of consumptive research on human embryos**(We suggest this sentence is deleted)**
80. Advocates a ban on human cloning, irrespective of the aim pursued and the techniques or methods used, and calls on the Commission to examine the legal scope for an EU ban on cloning; **(We suggest this paragraph is replaced by: Advocates a ban on human reproductive cloning, and calls on the Commission to examine the legal scope for an EU ban on reproductive cloning;)**

83. Acknowledges that the issue of whether it is possible to regulate embryo research at European level is controversial from a legal point of view and, even if EU-wide rules were legally possible, it would only be realistic to adopt certain basic rules, so that, for the foreseeable future, it will be up to each Member State to either prohibit or authorise embryo research; stresses, however, that if such research is authorised, respect for human dignity implies that rules must be drawn up to prevent the risk of unlawful experiments in which human embryos are used as tools; **(This is highly debatable. If some Members States do allow research using embryonic stem cells, their position should be respected as there is no consensus at the Community level on these issues. Therefore there is no reason not to fund researches which are conducted in countries where they are allowed. We suggest the last phrase be replaced by: however, that if such research is authorised, respect for human dignity implies that rules must be drawn up to prevent unlawful experiments in which human embryos are used)**
84. Takes the view that, out of respect for the ethical convictions of many European citizens and for the legal orders of the Member States, research activities should receive EU funding only if they are not regarded by any Member State as violating the fundamental ethical principles of its constitution; **(This rule as never been applied in the past for other situations. It is impossible to apply it without a very large debate among member states citizens. We suggest this paragraph is deleted)**