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Decisions on the subject of human cloning and embryo research adopted by the European Parliament and the Council

In a resolution of 14 April 1997, the European Parliament states:

'in the clear conviction that the cloning of human beings, whether experimentally, in the context of fertility treatment, preimplantation diagnosis, tissue transplantation or for any other purpose whatsoever, cannot under any circumstances be justified or tolerated by any society, because it is a serious violation of fundamental human rights and is contrary to the principle of equality of human beings as it permits a eugenic and racist selection of the human race, it offends against human dignity and it requires experimentation on humans.' (OJ C 115, 14.4.1997, p. 93)

The views expressed in its resolution of 15 January 1998 are equally unambiguous:

'whereas human cloning is defined as the creation of human embryos having the same genetic make-up as another human being, dead or alive, at any stage of its development from the moment of fertilisation, without any possible distinction as regards the method used.'

'Calls on each Member State to enact binding legislation prohibiting all research on human cloning within its territory and providing for criminal sanctions for any breach'. (OJ C 34, 15.1.1998, p. 164)

Amendment by Parliament concerning the 5th RTDD Framework Programme:

*'No research activity which modifies the human genetic heritage by manipulation of germ cells or manipulation at another stage in embryonic development, which modification might become part of the genetic heritage, will take place under the present framework programme. In the same way, no activity is planned in the area of human cloning, i.e. the production of human embryos, with the same genetic information as another human being or a deceased person. **In***

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the light of the differing approaches in the European Union to the ethical problems connected with these technologies, no research will be conducted which results in the destruction of embryos'. (Minutes of the sitting of the European Parliament of 17 June 1998. Amendment 36)

**Excerpts from the Directive on the Legal Protection of Biotechnological Inventions
(Biopatents) Directive:**

Recital 40: *Whereas there is a consensus within the Community that interventions in the human germ line and the cloning of human beings offends against ordre public and morality; whereas it is therefore important to exclude unequivocally from patentability processes for modifying the germ line genetic identity of human beings and processes for cloning human beings;*

Recital 41: *Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being;*

Article 6(1): *Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*

Article 6(2): *On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:*

- (a) processes for cloning human beings;*
 - (b) processes for modifying the germ line genetic identity of human beings;*
 - (c) uses of human embryos for industrial or commercial purposes;*
- (OJ L 213, 30.7.1998, p.13)**

A **Council memorandum** on the common position on the Biopatents Directive, states, at point 35, that:

'At (a) in paragraph 2, the Council replaced 'procedures for human reproductive cloning' with 'procedure for the cloning of human beings', since it thought the adjective 'reproductive' could be too restrictive. It was understood that the words 'human being' referred to human being from the embryonic state'.

When a patent on GM human embryos was announced in spring 2000, the newly elected Parliament reaffirmed its rejection of the cloning of human beings at any stage of human development:

Resolution of 30 March 2000 on the decision of the European Patent Office on the cloning of human beings:

Paragraph 4: *'Underlines its fundamental position regarding the application of biotechnology on human beings, especially the refusal of interventions in the human germ line, the refusal of cloning of the human being in all phases of its development and the refusal of research on human embryos, which destroys the embryos'.*

In September 2000, the EP adopted a resolution about the plans of the British government on cloning human embryos in which these plans are clearly rejected:

Excerpts from the European Parliament's resolution on human cloning (September 2000):

- C. whereas there are other ways than embryonic cloning of curing serious illnesses, such as those that involve taking stem cells from adults or from the umbilical cords of new-born babies, and other external causes of disease which require research, (...)
- H. 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, (...)
- 2. Considers that ‘therapeutic cloning’, which involves the creation of human embryos solely for research purposes, poses a profound ethical dilemma, irreversibly crosses a boundary in research norms and is contrary to public policy as adopted by the European Union; (...)
- 5. Urges maximum political, legislative, scientific and economic efforts to be aimed at therapies that use stem cells taken from adult subjects; (...)
- 7. Renews its call for human artificial insemination techniques that do not produce an excess number of embryos in order to avoid generating superfluous embryos; (...)
- 10. Repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development; (...)

On the 6th September 2001, the EP adopted a report on the proposal for a European Parliament and Council directive setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components:

21 (a) Work with human stem cells is a very promising branch of medical research, even if it is not yet possible to say what success this research will have for patients. An alternative to the ethically controversial and in some Member States illegal collection of stem cells from human embryos is research on adult stem cells, for example from the blood of adults or from the umbilical cord of newborn infants. The exploration and use of these alternatives is impeded by various regulations in the Member States. The Commission will therefore propose regulations, within the framework of a proposal on the quality and safety of tissue and cells of human origin, to ensure the safe use of adult stem cells and to help promote these alternatives.

Decision of the EP on the 6th Research Framework Programme (first reading, 14.11.2001)

Amendments 22, 332, 333 and 334
Article 3

2. The following fields of research shall not be financed under this framework programme:

- *research activity aiming at human cloning for reproductive purposes;*
- *creation of embryos for research purposes including somatic cell nuclear transfer;*
- *research activity resulting in a modification of the genetic heritage of human beings, which could make such changes hereditary (cancer treatment of the gonads can be financed);*

Another amendment was adopted in the scope of the motion for a resolution "Life sciences and biotechnology" in November 2002 (Report Damiao)

Repeats its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development and urges the Commission and the Member States to work towards this end

A proposal for a directive on quality and safety of tissues and cells was voted in the European Parliament in first reading in April 2003. The following amendments were adopted by the European Parliament:

Art. 13 (new) As far as compliance with legal rules protecting human dignity is concerned, the Commission and the Member States should endeavour to create a code of conduct, if possible at United Nations level. International legislation in this sector should comply at least with the following principles:

- *a ban on making the human body or its parts a source of financial gain,*
- *the principle of informed consent,*
- *a ban on producing human embryos with the same genetic data as another human being.*

Art 2b (new) Member States shall at least prohibit:

- research on human cloning for reproductive purposes,*
- research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei.*

Art 15 paragraph 6a (new) Cloned human embryos, and human - animal hybrid embryos produced by cloning, aggregation or any other procedure, and tissues and cells derived from them, shall be excluded as sources of material for transplantation.

*Annex IV paragraph 2.2a **CLONED HUMAN EMBRYOS AND HUMAN – ANIMAL HYBRID EMBRYOS** Cloned human embryos, and human - animal hybrid embryos produced by cloning, aggregation or any other procedure, and tissues and cells derived from them, shall be excluded as sources of material for transplantation.*