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REPORT

on the proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)
(COM(2003) 390 – C5-0349/2003 – 2003/0151(CNS))

Committee on Industry, External Trade, Research and Energy

Rapporteur: Peter Liese

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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PROCEDURAL PAGE

By letter of 25 July 2003 the Council consulted Parliament, pursuant to Article 166(4) of the EC Treaty, on the proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006) (COM(2003) 390 – 2003/0151(CNS)).

At the sitting of 1 September 2003 the President of Parliament announced that he had referred the proposal to the Committee on Industry, External Trade, Research and Energy as the committee responsible and the Committee on Legal Affairs and the Internal Market and to the Committee on the Environment, Public Health and Consumer Policy for their opinions (C5-0349/2003).

The Committee on Industry, External Trade, Research and Energy had appointed Peter Liese rapporteur at its meeting of 10 July 2003.

The committee considered the Commission proposal and draft report at its meetings of 9 September, 7 Octobre, 3 and 4 Novembre 2003.

At the last meeting it adopted the draft legislative resolution by 28 votes to 22 with 2 abstentions.

The following were present for the vote: Luis Berenguer Fuster (chairman), Peter Michael Mombaur, Yves Piétrasanta and Jaime Valdivielso de Cué (vice-chairmen), Peter Liese (rapporteur), Gordon J. Adam (for Massimo Carraro), Nuala Ahern, Konstantinos Alyssandrakis, Sir Robert Atkins, Bastiaan Belder (for Yves Butel), Mario Borghezio (for Gian Paolo Gobbo), David Robert Bowe (for Harlem Désir), Hiltrud Breyer, Marco Cappato, Gérard Caudron, Giles Bryan Chichester, Nicholas Clegg, Willy C.E.H. De Clercq, Concepció Ferrer, Francesco Fiori (for Guido Bodrato), Neena Gill (for Gary Titley), Norbert Glante, Michel Hansenne, Malcolm Harbour (for Umberto Scapagnini), Anne Elisabet Jensen (for Colette Flesch pursuant to Rule 153(2)), Hans Karlsson, Bashir Khanbhai, Werner Langen, Rolf Linkohr, Erika Mann, Eryl Margaret McNally, Hans-Peter Martin (for Myrsini Zorba), Marjo Matikainen-Kallström, Ana Clara Maria Miranda de Lage, Elizabeth Montfort, Angelika Niebler, Giuseppe Nisticò (for W.G. van Velzen), Seán Ó Neachtain, Reino Paasilinna, Paolo Pastorelli, Elly Plooij-van Gorsel, John Purvis, Godelieve Quisthoudt-Rowohl, Daniela Raschhofer, Imelda Mary Read, Mechtild Rothe, Christian Foldberg Rovsing, Paul Rübig, Konrad K. Schwaiger, Esko Olavi Seppänen, Claude Turmes and Alejo Vidal-Quadras Roca.

The opinion of the Committee on Legal Affairs and the Internal Market is attached. The Committee on the Environment, Public Health and Consumer Policy decided on 1 October 2003 not to deliver and opinion.

The report was tabled on 4 November 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a Council decision on amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)
(COM(2003) 390 – C5-0349/2003 – 2003/0151(CNS))

(Consultation procedure)

The European Parliament,

– having regard to the Commission proposal to the Council (COM(2003) 390)[1],

– having regard to Article 166(4) of the EC Treaty, pursuant to which the Council consulted Parliament (C5-0349/2003),

– having regard to Council Decision 1513/2002/EC of 27 June 2002 concerning the Sixth Framework Programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 - 2006)[2]

– having regard to Council Decision 834/2002/EC of 30 September 2002 adopting a specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006)[3]

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on Industry, External Trade, Research and Energy and the opinion of the Committee on Legal Affairs and the Internal Market (A5-0369/2003),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;

3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;

4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;

5. Instructs its President to forward its position to the Council and Commission.

[1] Not yet published in OJ.
[2] OJ L 232, 29.8.2002, p. 1.
[3] OJ L 294, 29.10.2002, p. 1.

Text proposed by the Commission	Amendments by Parliament

Amendment 1
RECITAL 4

(4) There is a great diversity among Member States concerning the ethical acceptability of various research fields and this is reflected in the national laws in accordance with the principle of subsidiarity. In particular, regulation and legislation ***of*** research using human embryos and human embryonic stem cells is handled very differently among Member States. ***The specific programme already provides that national provisions apply and no research forbidden in any given Member State will be supported by Community funding to a legal entity established in that State***.	(4) There is a great diversity among Member States concerning the ethical acceptability of various research fields and this is reflected in the national laws in accordance with the principle of subsidiarity. In particular, regulation and legislation ***regarding*** research using human embryos ***created for the purpose of IVF and not used for this purpose any more (i.e. supernumerary embryos)*** and human embryonic stem cells is handled very differently among ***the*** Member States. ***Therefore this proposal in no way affects national laws concerning embryonic stem cells. Nevertheless, Member States which allow research on human embryos and human embryonic stem cells with support from EU funding will be expected to have effective regulation in place.***

Justification

1. It needs to be made clear that we are talking about human embryos created for the purpose of in vitro fertilisation which are no longer likely to be used for this purpose.

2. The reference to the effect that no research forbidden in a Member State will be supported by European research policy should be deleted, because it creates more confusion than clarity. Anything prohibited by law in a Member State cannot be supported in any case, whatever the EU says.

3. It needs to be made clear that this proposal does not seek to harmonise rules on research with embryos and embryonic stem cells in the Member States, nor are any other efforts being made towards such harmonisation. Nevertheless, a general reference should be included to the effect that there is a need for rules to be adopted in this area by the Member States and that effective regulation is a pre-requisite for EU funding of research involving human embryos.

Amendment 2
RECITAL 5

(5) ***In light of the current state of***	(5) ***Articles 163 and following of the EC***

knowledge on human embryonic stem cells, new human embryonic stem cell lines, derived from human supernumerary embryos, are required.	***Treaty establish Community competencies with regard to research; these provisions state that the Community may complement the activities of the Member States with a view to achieving the objective of strengthening the scientific and technological bases of European industry, encouraging international competitiveness and promoting research activities. The use of human embryonic stem cells for research purposes should be strictly limited.***

Amendment 3

RECITAL 5 a (new)

	(5 a) The destruction of embryos in order to produce human embryonic stem cell lines must be subject to the prior agreement of the parents.

Justification

This conforms to standard practice. There is already the requirement that agreement must be obtained for organ-removal and blood and tissue donations.

Amendment 4
RECITAL 5 b (new)

	(5 b) The aims of stem cell research, especially the alleviation and cure of diseases which are until now not or not sufficiently treatable, are to be supported.

Justification

It is important to remember why the EU will be providing funding for this area of research.

Amendment 5

RECITAL 6

(6) This decision is intended to apply specifically to Community funding of research activities ***involving the procurement of*** stem cells from ***human***	(6) This decision is intended to apply specifically to Community funding of research activities ***using*** stem cells ***procured*** from embryos ***that have been produced*** as a

embryos ***created before 27 June 2002*** as a result of medically-assisted in vitro fertilisation designed to induce pregnancy and were no longer to be used for that purpose (supernumerary embryos). This decision amends the specific programme by introducing several conditions for deciding on the Community funding of such research.	result of medically-assisted in vitro fertilisation designed to induce pregnancy and were no longer to be used for that purpose (supernumerary embryos). This decision amends the specific programme by introducing several conditions for deciding on the Community funding of such research.

Justification

This will improve the quality of stem cell lines.

Amendment 6
RECITAL 6 a (new)

	(6 a) According to an overwhelming majority of scientists, a transplantation of human embryonic stem cells to patients during the time frame of the 6th Research Framework Programme (until the end of 2006) is not possible for purely scientific reasons, because this approach is mainly in the stage of basic research and a transplantation at the current moment would lead to non-calculable risks for the recipients.

Justification

Leaving aside the ethical debate, it will not be possible in the short term to transfer embryonic stem cells to patients, since no solution has been found to the risk of malignant mutation and rejection.

Amendment 7

RECITAL 6 b (new)

	(6 b) This proposal concerns the use of human embryos for research only and not for therapeutic purposes. Research on human embryonic stem cells is desirable for developing innovative treatments and, in particular, for developing treatments using adult stem cells.

Justification

Many scientists argue that basic research on human embryonic stem cells is necessary, even if the aim is to develop treatments using adult stem cells.

Amendment 8
RECITAL 7

(7) The present conditions are based on the principles established by the European Group on Ethics, especially the fundamental ethical principles underlined in the opinion No. 15: the principle of respect for human dignity (which requires provisions of guarantees against risks of arbitrary experimentation); the principle of human autonomy which entails the giving of informed consent and the protection of personal data; the principle of justice and of beneficence (namely with regard the improvement and protection of health); the principle of freedom of research (which should be balanced against other principles) and; the principle of proportionality (non-availability of adequate alternative methods in view of the scientific objectives to be reached).	(7) The present conditions are based on the principles established by the European Group on Ethics, especially the fundamental ethical principles underlined in the opinion No. 15: the principle of respect for human dignity (which requires provisions of guarantees against risks of arbitrary experimentation); the principle of human autonomy which entails the giving of informed consent and the protection of personal data; the principle of justice and of beneficence (namely with regard the improvement and protection of health); the principle of freedom of research (which should be balanced against other principles) and; the principle of proportionality (non-availability of adequate alternative methods in view of the scientific objectives to be reached). ***Furthermore, the experience from other scientific communities is being used.***

Justification

Since worldwide exchange takes place in the field of stem cell research, experience in other scientific communities must be taken into account. In your rapporteur's view the most sensible alignment in this connection is one with the USA.

Amendment 9
RECITAL 10 a (new)

	(10a) The existence of so-called supernumerary embryos after artificial fertilisation constitutes an ethical dilemma, as the transplantation of such embryos to others than the genetic parents (embryo adoption) as well as the simple "letting die off" of those embryos and placing them at disposal for research purposes is connected with ethical

	problems. As a consequence, an effort should be made to reduce the number of supernumerary embryos in the future, and the responsibility for this is with the Member States.

Justification

This amendment refers to Amendment 85 to the Caudron report adopted unanimously by Parliament at first reading. The problem of so-called 'supernumerary' embryos must be tackled at its root. However, the regulation of in vitro fertilisation is a national responsibility.

Amendment 10

ANNEX, PARAGRAPH 2, POINT (B)

(b) the human embryos used for the procurement of stem cells must ***have been created before 27 June 2002 as a result of medically-assisted in vitro fertilisation designed to induce pregnancy, and were no longer to be used for that purpose***;	(b) the human embryos used for the procurement of stem cells must ***be 'supernumerary' early-stage (i.e. up to 14 days) human embryos (embryos genuinely created for the treatment of infertility so as to increase the success rate of IVF but no longer needed for that purpose and when destined for destruction); such research may be funded provided that it is legally permitted in the Member State(s) where it will be conducted under the rules and strict supervision of the competent authority/ies***;

Justification

Imposing cut-off dates on research means arbitrarily preventing future research developments. The text of this amendment has already been adopted in plenary by the European Parliament by 317 votes to 190, with 28 abstentions at first reading of the Caudron report on the sixth research framework programme.

Amendment 11

ANNEX , PARAGRAPH 2, POINT (D)

(d) all other alternative methods (including existing or adult stem cell lines) must have been examined and demonstrated not to be sufficient for the purposes of the research in question;	***deleted***

Justification

Research using human embryonic stem cells lines as foreseen in the sixth framework programme decision has the potential to provide radically new forms of treatment for serious disease and disability. The availability and quality of human embryonic stem cell lines may be crucial to the success of this research and subsequent medical advances.

Amendment 12
ANNEX, PARAGRAPH 2, POINT (E)

(e) the free, express, written and informed consent of the donor(s) should ***be*** provided in accordance with national legislation prior to the ***start of the research activities***;	(e) the free, express, written and informed consent of the donor(s) should ***have been*** provided in accordance with national legislation prior to the ***procurement of the cells***; ***where embryos are to be destroyed in order to produce human embryonic stem cell lines, the prior agreement of the parents must be secured;***

Justification

Necessary clarification of Commission text. See also amendment to recital 5.

Amendment 13

ANNEX, PARAGRAPH 2, POINT (F)

(f) no monetary compensation ***or other*** benefit in kind ***must*** be granted or promised for the donation;	(f) no monetary compensation***,*** benefit in kind ***or other consideration may*** be granted or promised for the donation ***of embryos used for the recovery of stem cells***;

Justification

It is necessary here to specify very clearly both the concept of donation and the consequent personal advantage to the donor.

Amendment 14
ANNEX, PARAGRAPH 2, POINT (G)

(g) the protection of personal data, including the genetic data, of the donor(s) must ***be*** ensured;	(g) the protection of personal data, including the genetic data, of the donor(s) must ***have been*** ensured ***during the procurement***;

Justification

Necessary clarification of Commission text.

Amendment 15
ANNEX, PARAGRAPH 2, POINT (G) A (NEW)

(ga) In order to monitor these conditions, the Commission sets up a European register of embryonic stem cells; in doing this, the Commission uses the experience of the NIH;

Justification

The Commission has already announced, in its second call for expressions of interest on the 6th Framework Research Programme, that it will fund a European register of embryonic stem cells. Incorporating this plan in the text of this proposal has the advantage that the action of the Commission will have the political support of the European Parliament and the Council, and of ensuring greater legal certainty.

Amendment 16

ANNEX, PARAGRAPH 3

The scientific evaluation and the ethical review organised by the Commission of the research proposals shall include verification of these conditions. The conditions set out in point (c) ***and (d)*** shall be assessed ***during the scientific evaluation***.	The scientific evaluation and the ethical review organised by the Commission of the research proposals shall include verification of these conditions. The conditions set out in point (c) shall be assessed ***by an independent scientific body created for this purpose including members involved in research with other kinds of cell research***.

Justification

Since the issues addressed in point (c) are very complex technical matters, a special body should be set up for this purpose. Scientists who do not themselves work with stem cells might be unable to answer the questions raised.

Amendment 17

ANNEX, PARAGRAPH 3 a (new)

Projects with adult somatic stem cells and umbilical cord blood cells should be encouraged towards research involving other types of stem cells without excluding

comparative studies.

Justification

It relates to the 'Nistico amendment' adopted by Parliament at the first reading of the Caudron report. Many projects with adult stem cells have hitherto not been funded by the Commission. Parliament should express its support once again for this area of research.

Amendment 18

ANNEX, PARAGRAPH 4 a (new)

Research on the use of human stem cells may be financed depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved; research using adult stem cells and reprogrammed adult cells should get priority for financing; there is no restriction on financing research on stem cell lines already existing in scientific laboratories. In addition, research on embryo or fetal stem cells deriving from spontaneous or therapeutic abortion may be funded.

Justification

While privileging research on adult stem cells the intention is not to prohibit research on embryonic cells. The text of this amendment has already been adopted in plenary by the European Parliament by 422 votes to 99, with 8 abstentions, at first reading of the Caudron report on the sixth research framework programme.

Amendment 19

ANNEX, PARAGRAPH 6

'… A list of research projects involving the use of all types of human embryonic stem cells funded under the sixth framework programme will be published yearly by the Commission.'	'… A list of research projects involving the use of all types of human ***adult or*** embryonic stem cells funded under the sixth framework programme will be published yearly by the Commission. ***In the case of research projects with embryonic stem cells, such publication must include a justification stating why other procedures were not usable.'***

Justification

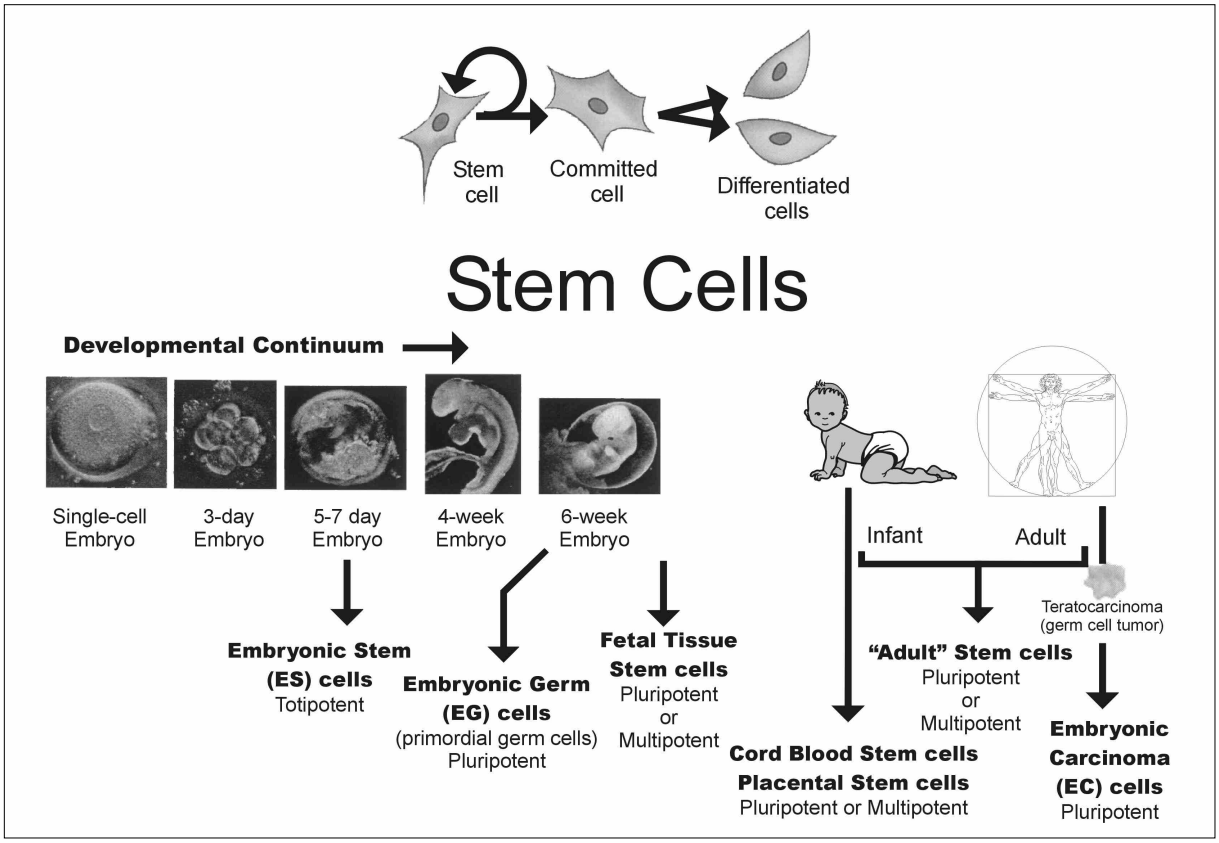
This addition is required, the better to assess developments in efforts to promote research under the sixth framework programme.

EXPLANATORY STATEMENT

The proposed Council decision concerns rules for the funding of research with human embryos and embryonic stem cells using resources from the Sixth Research Framework Programme.

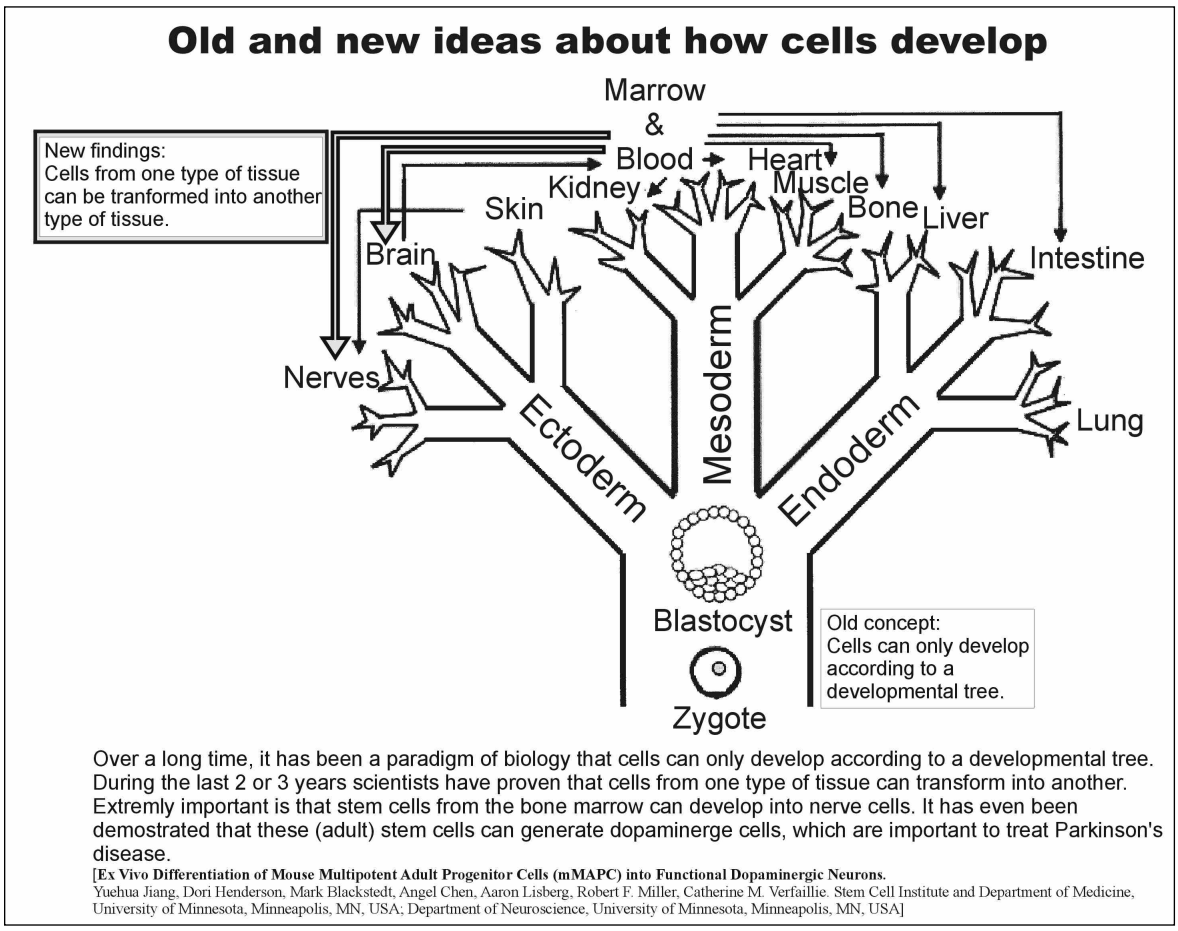
What are stem cells?

Stem cells are cells which have not yet developed their final function. They occur at all stages of human development.



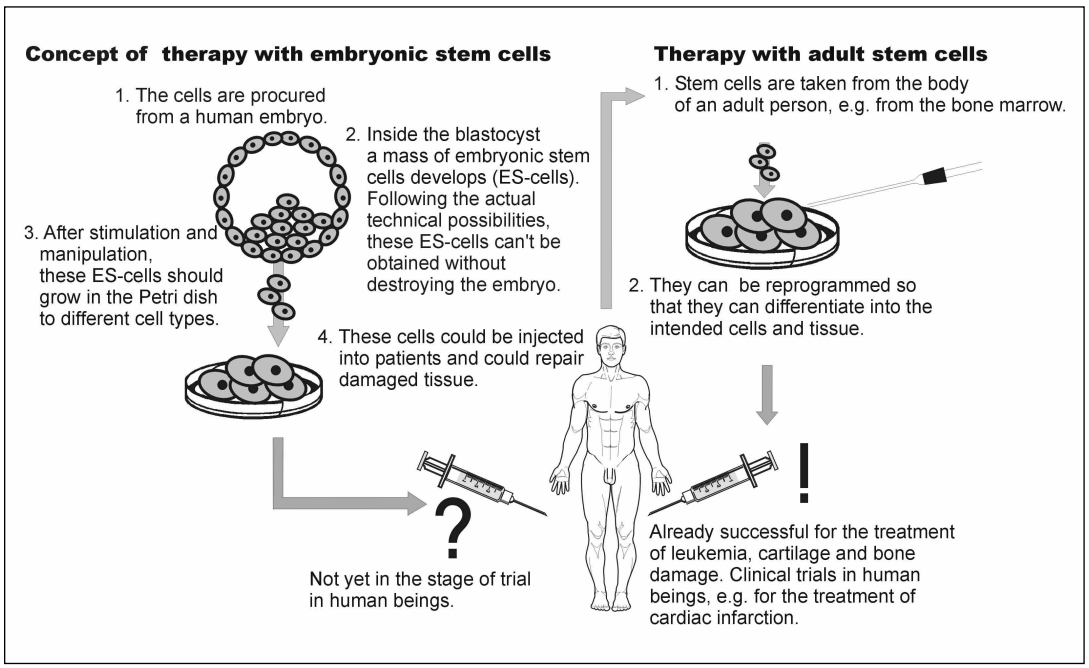
The purpose of stem cell research is to develop therapies for illnesses resulting from the death of specific cells ('reconstructive medicine'). One frequently quoted example is the possible treatment of Parkinson's disease using stem cells. In Parkinson's disease, a particular area of the brain dies off, and stem cell research suggests that stem cells could be used to recreate the cells of this area of the brain.

Until a few years ago it was not realised that stem cells occur in almost all organs of the human body (including the brain). It has since also been shown that not only embryonic stem cells but also adult stem cells, e.g. those from the bone marrow, can be transformed into various brain and nerve cells, e.g. in the dopaminergic cells which are of potential use in the treatment of Parkinson's disease (see diagram 2)



Embryonic stem cells v. adult stem cells

Embryonic stem cells have the advantage from a scientific point of view that they can be reproduced almost indefinitely in the laboratory. However, that becomes a problem at the stage when a therapy is to be practised on patients, because cells which reproduce themselves indefinitely present a cancer risk to the recipient. Cancers have occurred with alarming frequency in animal experiments. There is also the risk of rejection by the recipient, since the embryonic stem cells have a different genetic makeup from the recipient.



Adult stem cells have the drawback that they are hard to reproduce. On the other hand, they have the advantage that there is normally no risk of rejection, since the cells come from the patient him- or herself. There is also practically no cancer risk with adult stem cells. It is important to note that adult stem cell research, unlike embryonic stem cell research, has already resulted in successful therapies on human patients. For detailed information see the following websites: www.eutop.de/ct (Speech by Prentice) and www.peter-liese.de .

The ethical debate concerning embryonic stem cell research

Research with human embryonic stem cells is controversial, since embryonic stem cells cannot be procured without destroying human embryos. In some Member States, embryos are protected as human beings by law, and in some cases even by the constitution (Ireland, Austria, Germany, Poland). In some Member States and candidate countries (e.g. Italy, Slovakia), based on this premise are being debated in parliament. On the other hand, some Member States defend the position that embroyos are not human beings at all and that they merely possess a special status distinguishing them from things. This concept was first put into practice in Great Britain and has been taken over by a number of EU Member States, at least with regard to what are known as 'supernumerary embryos'.

In your rapporteur's opinion it is neither possible nor necessary to resolve the conflict which exists between Member States, and within Member States, on the status of the human embryo. This is not the task of the European Union, and certainly not the task of the proposal for a regulation before us. At least in the short term, there is no prospect of a compromise on this issue. This proposal is concerned solely with what type of research may be funded under the Sixth Research Framework Programme. On this your rapporteur considers that a compromise is achievable if all sides make an effort.

Procedure

The Sixth Research Framework Programme provides for support to be given to cell therapy, and in particular to stem cell therapy.

It clearly excludes research activities seeking to breed human embryos solely for research purposes or to procure stem cells, including by somatic cell nuclear transfer.

What other types of stem cell research may be supported, and whether support may also be granted for the procurement of embryo stem cells and research on 'supernumerary' embryos, is not clearly laid down either in the Framework Programme or in the specific programme. In September 2002 the Council of Ministers, after long negotiations with the Commission and the European Parliament, imposed a one-year moratorium on the funding of research activities which involve the use of human embryos and human embryonic stem cells. This moratorium excluded banked or isolated human embryonic stem cells in culture, though the specific programme itself did not define what was to be understood by this term. On 9 July the Commission submitted a proposal, which essentially provides that the procurement of new embryonic stem cell lines from 'supernumerary' embryos may be funded if these embryos were created before 27 June 2002.

The reactions to the Commission proposal were very varied. The UK BioIndustry Association (BIA) welcomed the proposal with the words: 'This is an important and welcome step that will encourage development in this field across the EU'.

The commission of the European Bishops' Conference firmly rejected the proposal. The Austrian research minister Elisabeth Gehrer expressed a similar view: 'Community funds should rather be used to search for other alternatives and for ethically unobjectionable research on adult stem cells.' Many shades of opinion were expressed between these two extremes.

Your rapporteur's point of view

In your rapporteur's view there are good reasons for excluding research with human embryos and human stem cells from Community funding altogether.

In view of the fact that many sensible projects in other areas are not being supported because insufficient funds were available, it is quite possible to justify not using resources from the Sixth Framework Research Programme to support embryonic stem cell research .

However, following the debates which have taken place so far in Committee on Industry, External Trade, Research and Energy and in the European Parliament's plenary sessions, there is no prospect of obtaining a majority on such a position.

Your rapporteur therefore proposes a compromise which amounts in essence to supporting embryonic stem cell research while imposing strict criteria on such support. This also reflects in principle the general line taken by the Commission. However, a critical look needs to be taken at a number of the details of the Commission proposal.

Detailed comments on the Commission proposal

1. Under the Council Decision of 30 September 2002, the Commission was mandated to submit a proposal on the funding of research activities which involve the use of **human embryos and human embryonic stem cells**. The proposal before us, however, covers only the creation of human embryonic stem cells from 'supernumerary embryos'. No rules are proposed for the embryonic stem cells as such. This might effectively undermine the spirit of the Commission proposal. The Council mandate also clearly called for rules governing embryos and embryonic stem cells. That means specific rules should be laid down governing not only human embryos used for the procurement of human embryonic stem cells, but the whole of research with human embryos, even when intended for other purposes.

2. In point (d) of the Annex the Commission lays down that, before approval is given to a project involving the procurement of embryonic stem cells, all alternative methods should be examined. However, the examination procedure seems very unclear and, quite aside from any controversy, the European Parliament has always held the view that adult stem cells should have priority.

3. One important reason given in general for the procurement of new embryonic stem cells is that the stem cell lines hitherto available have been patented, and are therefore very expensive to obtain. For this reason the Commission proposes that participants in the research projects should **'use their best efforts'** to make the newly derived human embryonic stem cell lines available to the scientific community on a non-profit making basis for research purposes. The question then arises, however, whether the aim of the provision can really be achieved if such extremely vague wording is used.

Your rapporteur's proposal

Your rapporteur's proposal is based on the position taken by the European Parliament in October 2001 by the adoption of the 'Nistico amendment', whereby adult stem cells and the re-programming of adult cells should be given priority for research funding. However, support for embryonic stem cell research via the Sixth Framework Programme should be permissible.

In view of recent scientific developments and the need to reach a compromise, however, the proposal modifies this position. This is also influenced by the fact that the Nistico amendment failed to achieve a qualified majority in October 2001, so that efforts must be made to achieve a broader majority. It will be recalled that on 10 April 2003 the European Parliament voted on a motion for a resolution by Mrs Flemming and 32 other Members calling for a complete ban (i.e. not merely for exclusion from funding under the 6th Framework Programme) on research on 'supernumerary' embryos. This resolution was supported by 232 Members and opposed by 232 Members, showing that the European Parliament is split on this issue and that only a modified proposal has any chance of winning a broad majority.

Your rapporteur does not regard it as sensible to draw out the procedure any longer. The expiry of the moratorium at the end of 2003 will lead to further legal uncertainty for the researchers involved. Clear rules are urgently needed.

The most important research area in the world is beyond any doubt the USA. It is also there that the most public funds are made available to support research. While it is quite right to criticise the situation in the USA for its lack of any rules on privately financed research, it is also worthwhile looking closely at the practice of public support for research in the USA. The NIH, which provides by far the greatest amount of resources for medical and biotechnology research in the world, funds research with stem cell lines only if they were procured before 7 August 2001. The rules of the NIH were criticised by both sides following their adoption by the American government. Particularly fierce criticism came from conservative family rights and right-to-life groups, e.g. from :

Ken Connor, President of the Family Research Council: 'At its worst that represents the ethos of Dr (Josef) Mengele, who experimented on doomed twins at Auschwitz on the basis that they were going to die anyway.'

Criticism also came from the scientific community, though the decision was mostly seen as a step in the right direction:

James Thomson (University of Wisconsin): 'The field will now go forward. It won't be limited to just a few labs, even if there are only a few dozen cell lines. That's the most important thing.'

Patients' representatives reacted similarly. For example the actor Christopher Reeve, who was paralysed following a riding accident and hopes for a cure from embryonic stem cell research, said: 'It's a step in the right direction and I'm grateful to the President...'

Before the cut-off date of 7 August 2001, 78 embryonic stem cell lines had been created. For various reasons, only 12 of these are yet in a state to be sent to other parts of the world. However, these 12 lines can be used for hundreds of research projects throughout the world, including Europe, since a feature of stem cell lines is that they can be reproduced almost indefinitely. In the case of mouse embryonic stem cells, too, which provide a basis for research on human embryonic stem cells, there are not (as one might think) thousands of lines which have been researched worldwide, but only a very restricted number. This is not only a sensible approach in order to take account of ethical objections but also simplifies the comparability of research results. The celebrated stem cell researcher Hans Schöler, Professor at the University of Pennsylvania, who is unequivocally in favour of research on embryonic stem cells, advises in a letter to your rapporteur that 'the European Parliament should ensure that five human embryonic stem cell lines are available for research.'

The question naturally arises whether the 78 lines listed in the NIH's register are actually available to European researchers. In this connection it needs to be pointed out that these lines are in no way the property of the NIH or the American government, but can be made available worldwide by research teams. In fact, only a very small number of them originate in the USA. Most of them are stored in states which are among the participants in the Sixth Research Framework Programme (e.g. Sweden and Israel). At least some of these stem cell lines are available to researchers under the Sixth European RFP. Hans Wigzell, President of the Karolinska Institute, replied as follows to an e-mail from your rapporteur asking whether the stem cell lines in his institute could be used in the context of the 6th RFP:

We have a number of human stem cell isolates in various stages in relation to lines. The 5 you are mentioning probably relate to the ones that were in existence at the time President Bush put his deadline for US federal funding. Our stem cell lines can be made available to other European scientists in collaboration i.e. in research programmes of the type included in the 6th Framework programme.

Many research teams in the EU use embryonic stem cells listed in the NIH register (a list of examples may be requested at the rapporteur's office).

Wide-ranging research with embryonic stem cells is therefore entirely possible, even limiting oneself to the stem cell lines in the NIH register. **It is true that the restriction to NIH stem cell lines is a concession by those who favour such research to their critics. However, this compromise also undoubtedly represents a very large concession by the opponents of embryonic stem cell research to its supporters. European compromises are characterised by both sides having to make concessions. Your rapporteur therefore calls on both sides to accept this compromise.**

22 October 2003

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND THE INTERNAL MARKET

for the Committee on Industry, External Trade, Research and Energy

on the proposal for a Council decision amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European research area" (2002-2006)
(COM(2003) 390 – C5-0349/2003 – 2003/0151(CNS))

Draftsman: Giuseppe Gargani

PROCEDURE

The Committee on Legal Affairs and the Internal Market appointed Astrid Thors draftsman at its meeting of 11 September 2003.

Following the vote at the meeting of 20 October 2003, Astrid Thors decided to resign as a draftsperson and the draft opinion is presented by Giuseppe Gargani as the Chairman of the Comittee on Legal Affairs and the Internal Market.

It considered the draft opinion at its meetings of 01 October 2003 and 20 October 2003.

At the latter/last meeting it adopted the following amendments by 18 votes to 13.

The following were present for the vote Giuseppe Gargani (chairman and draftsman), Willi Rothley (vice-chairman), Ioannis Koukiadis (vice-chairman), Bill Miller (vice-chairman),Ulla Maija Aaltonen, Paolo Bartolozzi, Ward Beysen, Brian Crowley, Bert Doorn, Giovanni Claudio Fava (for François Zimeray), Janelly Fourtou, Marie-Françoise Garaud, Evelyne Gebhardt, Fiorella Ghilardotti, José María Gil-Robles Gil-Delgado, Malcolm Harbour, Lord Inglewood, Kurt Lechner, Klaus-Heiner Lehne, Peter Liese, Arlene McCarthy, Manuel Medina Ortega, Elena Ornella Paciotti (for Maria Berger), Bernd Posselt (for Rainer Wieland), Anne-Marie Schaffner, Astrid Thors (for Toine Manders), Marianne L.P. Thyssen, Diana Wallis, Phillip Whitehead (for Carlos Candal), Joachim Wuermeling, Stefano Zappalà.

AMENDMENTS

The Committee on Legal Affairs and the Internal Market calls on the Committee on Industry, External Trade, Research and Energy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
RECITAL 4

(4) There is a great diversity among Member States concerning the ethical acceptability of various research fields and this is reflected in the national laws in accordance with the principle of subsidiarity. In particular, regulation and legislation of research using human embryos and human embryonic stem cells is handled very differently among Member States. The specific programme already provides that national provisions apply ***and*** no research forbidden in any given Member State will be supported by Community funding ***to a legal entity established in that State***.	(4) There is a great diversity among Member States concerning the ethical acceptability of various research fields and this is reflected in the national laws in accordance with the principle of subsidiarity. In particular, regulation and legislation of research using human embryos and human embryonic stem cells is handled very differently among Member States. The specific programme already provides that national provisions apply***. Consequently*** no research forbidden in any given Member State will be supported by Community funding.

Justification

In view of the greatly different legal frameworks between Member States pertaining to research involving human embryos, it should be a matter for each individual Member State, in conformity with the principle of subsidiarity, to decide whether they wish to fund this type of research out of their own national funds.

Amendment 2

RECITAL 5

(5) ***In light of the current state of knowledge on human embryonic stem cells,***	(5) ***Articles 163 and following of the EC Treaty establish Community competencies***

[1] OJ C ... / Not yet published in OJ..

new human embryonic stem cell lines, derived from human supernumerary embryos, are required.	***with regard to research; these provisions state that the Community may complement the activities of the Member States with a view to achieving the objective of strengthening the scientific and technological bases of European industry, encouraging international competitiveness and promoting research activities.***

Amendment 3

RECITAL 6

(6) ***This decision is intended to apply specifically to Community funding of research activities involving the procurement of stem cells from human embryos created before 27 June 2002 as a result of medically-assisted in vitro fertilisation designed to induce pregnancy and were no longer to be used for that purpose (supernumerary embryos). This decision amends the specific programme by introducing several conditions for deciding on the Community funding of such research.***	(6) ***The Community's competencies with regard to research complement those of the Member States and the Community should make use of these complementary competencies essentially through initiatives to provide financial support and/or non-binding coordination or to support and complement national policies. This may never, even indirectly, equate to harmonisation of national provisions.***

Amendment 4

RECITAL 7

(7) ***The present conditions are based on the principles established by the European Group on Ethics, especially the fundamental ethical principles underlined in the opinion No. 15: the principle of respect for human dignity (which requires provisions of guarantees against risks of arbitrary experimentation); the principle of human autonomy which entails the giving of informed consent and the protection of personal data; the principle of justice and of beneficence (namely with regard the improvement and protection of health); the principle of freedom of research (which should be balanced against other principles) and; the principle of***	(7) ***Intervention by the Community on the basis of its complementary competencies should be limited to supplementing, supporting or coordinating the action of the Member States. In such areas negative delimitation of competence (e.g. the exclusion of harmonisation in certain areas) is common. The Community may only act to encourage cooperation between the Member States and, if necessary, to support and supplement their actions. The power to adopt legislative rules in these areas remains in the hands of the Member States, and intervention by the Community cannot have the effect of excluding***

proportionality (non-availability of adequate alternative methods in view of the scientific objectives to be reached).	***intervention by the Member States.***

Amendment 5

RECITAL 8

(8) ***These conditions should be assessed during the course of a scientific evaluation and an ethical review.***	(8) ***Article 168 of the EC Treaty stipulates that in implementing the multiannual framework programme, supplementary programmes may be decided on involving the participation of only those Member States which shall finance them, subject to possible Community participation, and therefore Community initiatives must be restricted to covering activities for which none of the Member States oppose the fact that they are funded from the Community budget. Therefore, Community initiatives must be restricted to covering activities for which all the Member States agree with (or at least for which none oppose) the fact that they are funded from the Community budget.***

Amendment 6

RECITAL 9

(9) In order for this research to benefit the scientific community at large, the participants in research projects should use their best efforts to make the newly derived human embryonic stem cell lines available to the scientific community for research purposes.	***deleted***

Justification

In view of the greatly different legal frameworks between Member States pertaining to research involving human embryos, it should be a matter for each individual Member State, in conformity with the principle of subsidiarity, to decide whether they wish to fund this type of research out of their own national funds.

Amendment 7

RECITAL 10

(10) In order to ensure transparency a list of research projects involving the use of human embryonic stem cells funded under the sixth framework programme should be published annually by the Commission.	***deleted***

Justification

In view of the greatly different legal frameworks between Member States pertaining to research involving human embryos, it should be a matter for each individual Member State, in conformity with the principle of subsidiarity, to decide whether they wish to fund this type of research out of their own national funds.

Amendment 8

ANNEX

In part 1.1 of annex I to Decision 2002/834/EC, the following text shall be inserted after the 17th paragraph.	In part 1.1 of annex I to Decision 2002/834/EC, the following text shall be inserted after the 17th paragraph.
"***In order to be funded by the Community***, research projects involving the procurement of stem cells from human embryos ***must also meet the following conditions:***	"Research projects involving the ***use of*** procurement of stem cells from human embryos ***shall not be funded by the Community***."
(a) prior to the start of research activities, participants must obtain ethical advice at local or national level in the countries where the research will be carried out;	
(b) the human embryos used for the procurement of stem cells must have been created before 27 June 2002 as a result of medically-assisted in vitro fertilisation designed to induce pregnancy, and were no longer to be used for that purpose;	
(c) the project must serve particularly important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to	

humans;

(d) all other alternative methods (including existing or adult stem cell lines) must have been examined and demonstrated not to be sufficient for the purposes of the research in question;

(e) the free, express, written and informed consent of the donor(s) should be provided in accordance with national legislation prior to the start of the research activities;

(f) no monetary compensation or other benefit in kind must be granted or promised for the donation;

(g) the protection of personal data, including the genetic data, of the donor(s) must be ensured;

(h) where appropriate, the participants in research projects must follow quality and safety standards on donation, procurement and storage in accordance to the state of the art, in order to ensure in particular the traceability of these stem cells.

The scientific evaluation and the ethical review organised by the Commission of the research proposals shall include verification of these conditions. The conditions set out in point (c) and (d) shall be assessed during the scientific evaluation.

The opinions of the European Group on Ethics in Science and New Technologies, and in particular those relating to research involving the use of human embryonic stem cells will be taken into account.

The participants in research projects should use their best efforts to make the newly derived human embryonic stem cell lines available to the scientific community on a non-profit making basis for research purposes.

A list of research projects involving the use of all types of human embryonic stem cells funded under the sixth framework programme will be published yearly by the Commission".