



EUROPEAN PARLIAMENT

2009 - 2014

Committee on the Environment, Public Health and Food Safety

2011/2193(INI)

14.5.2012

AMENDMENTS

1 - 99

Draft report
Marina Yannakoudakis
(PE480.608v01-00)

Voluntary and unpaid donation of tissues and cells
(2011/2193(INI))

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PE489.459v01-00

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United in diversity

EN

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Amendment 1
Marisa Matias

Motion for a resolution
Citation 2

Motion for a resolution

– having regard to the Charter on Fundamental Rights of the European Union,

Amendment

– having regard to the Charter on Fundamental Rights of the European Union, *and in particular Article 1 on "Human dignity" and Article 3 on the "Right to the integrity of the person" which refers to the "prohibition on making the human body and its parts as such a source of financial gain"*,

Or. en

Amendment 2
Marisa Matias

Motion for a resolution
Citation 5 a (new)

Motion for a resolution

Amendment

- having regard to Regulation (EC) 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) 726/2004

Or. en

Amendment 3
Marisa Matias

Motion for a resolution
Citation 8

Motion for a resolution

– having regard to the World Health Organization's Guiding Principles on Human Organ Transplantation,

Amendment

– having regard to the World Health Organization's Guiding Principles on Human **Cell, Tissue and Human** Organ Transplantation,

Or. en

Amendment 4

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Citation 9 a (new)

Motion for a resolution

Amendment

- having regard to the Oviedo Convention on Human Rights and Biomedicine, and the additional protocol thereto on transplantation of organs and tissues of human origin,

Or. fr

Amendment 5

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Citation 11 a (new)

Motion for a resolution

Amendment

- having regard to the European Parliaments Resolution on the trade in human egg cells from March 10th 2005

Or. en

Amendment 6

Peter Liese, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Paolo Bartolozzi, Boguslaw Sonik, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital A

Motion for a resolution

A. whereas donated tissues and cells, such as skin, bones, tendons, corneas and haematopoietic stem cells, are increasingly used in medical therapies and as starting material for advanced therapy medicinal products (ATMP);

Amendment

A. whereas donated tissues and cells, such as skin, bones, tendons, corneas and haematopoietic stem cells, are increasingly used in medical therapies and as starting material for advanced therapy medicinal products (ATMP); ***whereas the Directive 2004/23 asks the Member States to endeavour to ensure voluntary and unpaid donation and endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis which is a clear legal obligation which can in the case where a Member State does not follow the principal lead to infringement procedure;***

Or. en

Amendment 7

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Recital H

Motion for a resolution

H. whereas public awareness and ***opinion*** play a very important role in increasing tissues and cells donation rates;

Amendment

H. whereas public awareness and ***the dissemination of clear, fair, scientifically based and conclusive medical information*** play a very important role in ***gaining public support and*** increasing tissues and cells donation rates;

Or. fr

Amendment 8
Frédérique Ries

Motion for a resolution
Recital H

Motion for a resolution

H. whereas public awareness and opinion play a very important role in increasing tissues and cells donation rates;

Amendment

H. whereas **targeted** public awareness and opinion, **particularly among the patient's immediate circle**, play a very important role in increasing tissues and cells donation rates;

Or. fr

Amendment 9
Marisa Matias

Motion for a resolution
Recital H

Motion for a resolution

H. whereas public awareness and opinion play a very important role in increasing tissues and cells donation rates;

Amendment

H. whereas public awareness and opinion **at national and European level** play a very important role in increasing tissues and cells donation rates;

Or. en

Amendment 10
Marisa Matias

Motion for a resolution
Recital H a (new)

Motion for a resolution

Amendment

Ha. whereas advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage, should be prohibited;

Amendment 11
Frédérique Ries

Motion for a resolution
Recital I

Motion for a resolution

I. whereas **only** 11 countries have policies in place to endeavour to promote self-sufficiency of tissues and cells;

Amendment

I. whereas, **while** 11 countries have **official** policies in place to endeavour to promote self-sufficiency of tissues and cells, **17 other countries have bilateral agreements with the same aim of ensuring national supplies of human tissues and cells;**

Or. fr

Amendment 12
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Recital K a (new)

Motion for a resolution

Amendment

Ka. whereas the removal of tissues and cells for the benefit of recipients may only be carried out under two conditions: it must be done with a medical or scientific and therapeutic aim, and all the elements removed must be donated without any payment being made;

Or. fr

Amendment 13
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Recital K b (new)

Motion for a resolution

Amendment

Kb. whereas the removal of tissue and cells must be subject to the following principles: anonymity (except in the case of removal from a living person for a relative), non-remuneration, consent, the obligation to share organs for transplant fairly among patients, and health safety for donors and recipients;

Or. fr

Amendment 14
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Recital L

Motion for a resolution

Amendment

L. whereas ***a healthcare intervention*** may only be ***carried out after the person concerned*** has given free and informed consent to it;

L. whereas ***tissues and cells*** may only be ***removed if the donor*** has given ***prior*** free and informed consent ***in writing*** to it; ***whereas this consent may be withdrawn at any time, and with no particular requirement as to format;***

Or. fr

Amendment 15
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Recital M

Motion for a resolution

Amendment

M. whereas the use of tissues and cells for application in the human body carries a risk of ***disease*** transmission ***and other potential adverse effects in*** recipients. That risk can be reduced by careful donor

M. whereas the use of tissues and cells for application in the human body carries a risk of transmission ***of disease to*** recipients. That risk can be reduced by careful donor selection, ***an evaluation of***

selection, testing of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice;

potential donors prior to procurement based on a risk/benefit analysis, testing and monitoring of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice;

Or. fr

Amendment 16

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Richard Seeber, Elena Oana Antonescu, Elisabetta Gardini, Boguslaw Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital M a (new)

Motion for a resolution

Amendment

Ma. Whereas the donation of some tissues and cells creates a severe risk for the donor, whereas this risk is particular high in egg-cell donation because of the hormone treatment which is necessary to prepare the donation;

Or. en

Amendment 17

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Richard Seeber, Elena Oana Antonescu, Elisabetta Gardini, Boguslaw Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital M b (new)

Motion for a resolution

Amendment

Mb. Whereas the Charter of Fundamental Rights which is the leading principle for the European Union and legally binding after entering into force of the Lisbon

Treaty prohibits making the human body and its parts as such a source of financial gain.

Or. en

Amendment 18

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Paolo Bartolozzi, Boguslaw Sonik, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital M c (new)

Motion for a resolution

Amendment

Mc. Whereas unpaid donation is not only an ethical principle but also necessary to protect the health of the donor and the recipient as the involvement of high amounts of money in the donation process may stimulate the donor to take risks and may hinder the disclosure of risks in his/her medical history.

Or. en

Amendment 19

Peter Liese, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Paolo Bartolozzi, Boguslaw Sonik, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital M d (new)

Motion for a resolution

Amendment

Md. Whereas there is a lot of evidence that allogenic cordblood transplantation is already successful for many patients and there are also serious reports that in some cases autologes treatment with this kind of cells can be successful.

Amendment 20

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Paolo Bartolozzi, Bogusław Sonik, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Recital M e (new)

Motion for a resolution

Amendment

Me. Whereas serious media again and again report that in the area of tissues and cells the principle of unpaid donation is violated.

Or. en

Amendment 21

Marisa Matias

Motion for a resolution

Recital M f (new)

Motion for a resolution

Amendment

Mf. whereas the capacity to trace cells and tissues from the donor to recipients and vice versa and long-term follow-up of living donors and recipients of cells and tissues are central elements of safety and quality management;

Or. en

Amendment 22

Margrete Auken

Motion for a resolution

Recital M g (new)

Motion for a resolution

Amendment

Mg. Whereas there is a significant amount of evidence that allogenic cordblood transplantation is successful for many patients; on the other hand, there is only very limited evidence about the potential success of autologous treatment with cordblood;

Or. en

Amendment 23
Margrete Auken

Motion for a resolution
Paragraph 1

Motion for a resolution

1. Welcomes the ***conclusions of the*** Second Report on Voluntary and Unpaid Donation of Tissues and Cells;

Amendment

1. Welcomes the Second Report on Voluntary and Unpaid Donation of Tissues and Cells ***which indicated that a significant amount of measures have been taken by Member States to ensure voluntary and unpaid donations, however, the report also showed that implementation is not yet complete; calls on Member States to fully implement the Directive and on the Commission to take all necessary measures to ensure this;***

Or. en

Amendment 24
Peter Liese, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution
Paragraph 1

Motion for a resolution

1. Welcomes the **conclusions** of the Second Report on Voluntary and Unpaid Donation of Tissues and Cells;

Amendment

1. Welcomes the **presentation** of the Second Report on Voluntary and Unpaid Donation of Tissues and Cells **which shows that a lot of activities are performed in the Member States to implement the principle of unpaid donation but also shows that still a lot needs to be done**

Or. en

Amendment 25
Frédérique Ries

Motion for a resolution
Paragraph 1 a (new)

Motion for a resolution

Amendment

1a. Notes with concern that half of Member States state that they regularly face a lack of human tissues and cells, particularly spinal marrow, gametes and tissues such as the cornea and the skin; believes that the policies and laws in force should therefore be reviewed, as they are not adequate to meet the challenge of self-sufficiency in the European Union;

Or. fr

Amendment 26
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Subheading 1

Motion for a resolution

Amendment

Compensation and altruism

Non-remuneration, consent and health safety

Amendment 27
Frédérique Ries

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Stresses that donation should be voluntary and unpaid, ***and take place in clearly defined legal and ethical contexts;***

Amendment

2. Stresses that donation should be voluntary and unpaid, ***as is consistently laid down by European laws on donations of blood and blood products, donations of tissues and cells and donations of organs, and at the same time stresses the need for the donation to be accompanied by fair reimbursement of the donor, which corresponds exactly to compensation caused by the medical treatment received;***

Amendment 28
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Stresses that donation ***should*** be voluntary and unpaid, and ***take place in clearly defined*** legal and ethical ***contexts;***

Amendment

2. Stresses that donation ***may only*** be ***carried out for medical or scientific and therapeutic purposes; that it is*** voluntary, ***anonymous (except in the case of procurement from a living person for a relative)*** and unpaid, and ***must be governed by protective*** legal and ethical ***rules which respect the integrity of the human person and are clearly defined;***

Amendment 29
Marisa Matias

Motion for a resolution
Paragraph 2

Motion for a resolution

2. Stresses that donation should be voluntary and unpaid, and take place in clearly defined legal and ethical contexts;

Amendment

2. Stresses that donation should be voluntary and unpaid, and take place in clearly defined legal and ethical contexts; ***underlines that the buying and selling of tissues and cells results in its commodification in the marketplace and devalues its socio-cultural importance in human relationships;***

Or. en

Amendment 30
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 3

Motion for a resolution

3. ***Endorses*** measures ***aimed at protecting*** living donors and ***ensuring*** that donation is ***made altruistically and voluntarily and considers the principle of altruism to be of fundamental importance, not merely because of the beneficial effect on the quality and safety of the donated cells and tissues, but also because it implies solidarity with the plight of others;***

Amendment

3. ***Calls on Member States to adopt protective*** measures ***for*** living donors and ***to guarantee*** that donation is ***anonymous (except in the case of procurement from a living person for a relative), voluntary, freely agreed to, informed and not remunerated;***

Or. fr

Amendment 31
Peter Liese, Marina Yannakoudakis, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution
Paragraph 3 a (new)

Motion for a resolution

Amendment

3a. Asks the Commission to carefully monitor the development in the Member States and to examine carefully any reports by actors in the civil society and media under violation of the principle and draw appropriate consequences if necessary infringement procedures.

Or. en

Amendment 32
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 3 b (new)

Motion for a resolution

Amendment

3b. Points out that no payment, irrespective of the form it takes, may be given to a person who agrees to the removal of parts of his body or the collection of its products, and that the costs relating to such removal or collection are the sole responsibility of the health establishment responsible for conducting the removal or collection;

Or. fr

Amendment 33
Frieda Brepoels

Motion for a resolution
Paragraph 3 c (new)

Motion for a resolution

Amendment

3c. Is nonetheless concerned about the

possible actual erosion of the principle of voluntary or unpaid donation, for example through the unproportional granting of fixed reimbursement of expenses without burden of proof, of recuperation time and of advantages in kind; is of the opinion that the principle of voluntary and unpaid donation in the 2004/03 guideline must be clarified and reinforced in order to discourage this erosion;

Or. nl

Amendment 34
Frédérique Ries

Motion for a resolution
Paragraph 4

Motion for a resolution

4. ***Calls on*** Member States to define the conditions under which financial compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating an organ, such as travel expenses, loss of earnings or medical costs, thereby prohibiting any financial incentives or disadvantages for a potential donor;

Amendment

4. ***Believes it is vital for all*** Member States to define the conditions under which financial compensation may ***reasonably*** be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred ***primarily*** in donating an organ, ***bone marrow or haematopoietic cells***, such as travel expenses, loss of earnings or medical costs, thereby prohibiting any financial incentives or disadvantages for a potential donor;

Or. fr

Amendment 35
Margrete Auken

Motion for a resolution
Paragraph 4

Motion for a resolution

4. Calls on Member States to define the conditions under which financial compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating *an organ*, such as travel expenses, *loss of earnings* or medical costs, thereby prohibiting any financial incentives *or* disadvantages for a potential donor;

Amendment

4. Calls on Member States to *clearly* define the conditions under which financial compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the *actual* expenses incurred in donating *tissues and cells*, such as travel expenses or medical costs, thereby prohibiting any financial incentives *and avoiding* disadvantages for a potential donor;

Or. en

Amendment 36

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Paragraph 4

Motion for a resolution

4. Calls on Member States to define the conditions under which *financial* compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating an organ, such as travel expenses, loss of earnings or medical costs, thereby prohibiting any financial incentives or disadvantages for a potential donor;

Amendment

4. Calls on Member States to define the conditions under which *fair and proportionate* compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating an organ, such as travel expenses, loss of earnings or medical costs, *and* thereby prohibiting any financial incentives or disadvantages for a potential donor;

Or. fr

Amendment 37

Marisa Matias

Motion for a resolution

Paragraph 4

Motion for a resolution

4. Calls on Member States to define the conditions under which financial compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating an organ, such as travel expenses, loss of earnings or medical costs, thereby prohibiting any financial incentives or disadvantages for a potential donor;

Amendment

4. Calls on Member States to define the conditions under which financial compensation may be granted, bearing in mind that compensation is strictly limited to conditions making good the expenses incurred in donating an organ, such as travel expenses, loss of earnings or medical costs, thereby prohibiting any financial incentives or disadvantages for a potential donor; ***such compensations must be transparent and regularly audited;***

Or. en

Amendment 38
Esther de Lange

Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution

Amendment 39
Marina Yannakoudakis, Frédérique Ries

Motion for a resolution
Paragraph 5

Motion for a resolution

5. Underlines nonetheless that the principle of altruism is not necessarily violated through the use of non-financial incentives such as benefits-in-kind, which

Amendment

4a. Calls on the Commission to report on current national practices and criteria for compensation of living donors, especially as regards egg cell donation;

Or. en

Amendment

deleted

can make donation less burdensome and more attractive, whilst ensuring that the human body shall not be a source of financial gain;

Or. en

Amendment 40

Peter Liese, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Elisabetta Gardini, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

**Motion for a resolution
Paragraph 5**

Motion for a resolution

Amendment

5. Underlines nonetheless that the principle of altruism is not necessarily violated through the use of non-financial incentives such as benefits-in-kind, which can make donation less burdensome and more attractive, whilst ensuring that the human body shall not be a source of financial gain;

deleted

Or. en

**Amendment 41
Marisa Matias**

**Motion for a resolution
Paragraph 5**

Motion for a resolution

Amendment

5. Underlines nonetheless that the principle of altruism is not necessarily violated through the use of non-financial incentives such as benefits-in-kind, which can make donation less burdensome and more attractive, whilst ensuring that the human body shall not be a source of financial gain;

deleted

Amendment 42
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 5

Motion for a resolution

Amendment

5. Underlines nonetheless that the principle of altruism is not necessarily violated through the use of non-financial incentives such as benefits-in-kind, which can make donation less burdensome and more attractive, whilst ensuring that the human body shall not be a source of financial gain;

deleted

Or. fr

Amendment 43
Margrete Auken

Motion for a resolution
Paragraph 5

Motion for a resolution

Amendment

5. Underlines nonetheless that the principle of altruism ***is not necessarily*** violated through the use of non-financial incentives such as benefits-in-kind, which can ***make donation less burdensome and more attractive, whilst ensuring that the human body shall not*** be a source of financial gain;

5. Considers that the principle of altruism ***risks to be*** violated through the use of non-financial incentives such as benefits-in-kind, which can be ***seen as another form*** of financial gain;

Or. en

Amendment 44
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Calls on Member States to ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified *or* trained *and competent* professionals;

Amendment

6. Calls on Member States to ensure that living donors are selected on the basis of *an evaluation of* their health and medical history, including a psychological evaluation if deemed necessary, *based on a risk-benefit analysis*, by qualified *and* trained professionals;

Or. fr

Amendment 45
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

6a. Calls on Member States to take measures to protect minors and adults under guardianship with regard to the removal of tissues and cells;

Or. fr

Amendment 46
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Subheading 2

Motion for a resolution

Traceability *and* transparency *issues*

Amendment

Anonymity, traceability, transparency *and information*

Or. fr

Amendment 47
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Stresses that the *principle* of transparency *is* key to achieving a high level of public support for donation; encourages Member States to work towards creating a transparent donation system which *upholds patient safety and increases traceability, which is particularly important when considering the donation of gametes;*

Amendment

7. Stresses that the *principles* of transparency *and safety are* key to achieving a high level of public support for donation; encourages Member States to work towards creating a transparent donation system which *is safe for donors and recipients;*

Or. fr

Amendment 48
Marisa Matias

Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution

7a. Calls all Member States to set up rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, as well as a system for the regulation of imports of human tissues and cells from third countries, ensuring that equivalent standards of quality and safety will apply;

Amendment

Or. en

Amendment 49
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Calls, *in this light*, on Member States to ensure the provision of *adequate* information and data *in order to enable* the public to make informed choices;

Amendment

8. Calls on Member States to *step up their public information and awareness-raising campaigns to promote the donation of tissues and cells and to* ensure the provision of *medical* information *that is clear, fair, scientifically based and conclusive* and data *enabling* the public to make informed choices;

Or. fr

Amendment 50
Claudiu Ciprian Tănăsescu

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Calls, in this light, on Member States to ensure the provision of adequate information and data in order to enable the public to make informed choices;

Amendment

8. Calls, in this light, on Member States to ensure the provision of adequate information and data in order to enable the public to make informed choices; *stresses that donors should be fully informed of the procedures used in this process and their moral, psychological, medical and social consequences;*

Or. ro

Amendment 51
Frédérique Ries

Motion for a resolution
Paragraph 9

Motion for a resolution

9. *Highlights the legal and ethical*

Amendment

9. Calls on Member States to *introduce*

*problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to **consider regulating this area** to prevent the **possible emergence** of an **online** black market;*

*regular and effective coordination to prevent the **development** of a black market **in gametes on the Internet posing real legal, ethical and public health problems; also highlights the fact that the existence of restrictive legal frameworks at the national and European level is certainly not the right response to give to the many patients in growing need of treatment;***

Or. fr

Amendment 52
Margrete Auken

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Highlights ***the legal and ethical problems posed by the existence of*** websites permitting people to sell or purchase gametes online; calls on Member States to ***consider regulating this area*** to ***prevent the possible emergence*** of an ***online black market;***

Amendment

9. Highlights ***that*** websites permitting people to sell or purchase gametes online ***clearly violate the principle of unpaid donation;*** calls on Member States to ***prohibit such practices, and calls on the Commission to take regulatory action should national action not suffice as such practices risk to undermine the quality and safety*** of ***tissues and cells;***

Or. en

Amendment 53
Marisa Matias

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to

Amendment

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to

consider regulating this area to prevent the possible emergence of an online black market;

take all necessary measures to regulate this area *so as* to prevent the possible emergence of an online black market;

Or. en

Amendment 54
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to *consider regulating this area to* prevent the possible emergence of an online *black* market;

Amendment

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to prevent the possible emergence of *such* an online market;

Or. fr

Amendment 55
Oreste Rossi

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to consider regulating this area to prevent the possible emergence of an online black market;

Amendment

9. Highlights the legal and ethical problems posed by the existence of websites permitting people to sell or purchase gametes online; calls on Member States to consider regulating this area to prevent the possible emergence of an online black market *and, where one exists, to suppress it*;

Or. it

Amendment 56
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 10

Motion for a resolution

10. Calls on Member States to *make a concerted effort to participate in the exchange of best practices in regards to dealing with shortages in* the supply of tissues and cells *and on how to best raise awareness of donating tissues and cells;*

Amendment

10. Calls on Member States to *step up exchanges of good practices, particularly with regard* to the supply of tissues and cells, *the protection of the quality of tissues and cells while they are being transported, raising awareness of donating and training health staff;*

Or. fr

Amendment 57
Dagmar Roth-Behrendt

Motion for a resolution
Paragraph 10 a (new)

Motion for a resolution

Amendment

10a. Expects all Member States to establish public tissue and cell databases;

Or. de

Amendment 58
Dagmar Roth-Behrendt

Motion for a resolution
Paragraph 10 b (new)

Motion for a resolution

Amendment

10b. Calls for European standards and requirements for private tissue and cell databases;

Or. de

Amendment 59
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 14

Motion for a resolution

14. Recognises the significant scientific advances made in the cord blood field **and the potential uses of cord blood to treat** diseases, including children's illnesses;

Amendment

14. Recognises the significant scientific advances made in the cord blood field, **which is a very promising therapeutic alternative in the treatment of many** diseases, including children's illnesses;

Or. fr

Amendment 60
Françoise Grossetête

Motion for a resolution
Paragraph 14 a (new)

Motion for a resolution

Amendment

14a. Stresses that clinical trials using cord blood stem cells for treatments linked to non-haematopoietic illnesses have taken place outside the European Union (in the United States of America and in countries in Asia); calls, therefore, on the European Commission and Member States to take the necessary measures to ensure that the European Union does not fall behind in this field, and in particular to create a regulatory framework that will increase the availability of cord blood stem cells for allogeneic and autologous uses;

Or. fr

Amendment 61
Frédérique Ries

Motion for a resolution
Paragraph 14 b (new)

Motion for a resolution

Amendment

14b. Is concerned that, currently, clinical trials using umbilical cord blood stem cells in therapy of non-hematological disorders are mostly taking place outside the European Union (i.e. USA and Asian countries). Therefore, calls upon the European Commission and the Member States to take appropriate measures to avoid risk for the EU of lagging behind in this field, including by creating a regulatory framework which stimulates increased availability of umbilical cord blood stem cells;

Or. en

Amendment 62
Esther de Lange

Motion for a resolution
Paragraph 14 c (new)

Motion for a resolution

Amendment

14c. Points out that currently clinical trials using umbilical cord blood stem cells are mostly taking place outside the European Union and calls upon the European Commission and the Member States to take appropriate measures to avoid the risk of the EU lagging behind in this field;

Or. en

Amendment 63
Peter Liese, Marina Yannakoudakis, Miroslav Mikolášik, Alojz Peterle, Elena Oana Antonescu, Richard Seeber, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner,

Renate Sommer, Anna Záborská

Motion for a resolution

Paragraph 15

Motion for a resolution

15. Underlines the importance of mothers donating cord blood and tissue at birth **either** into public **or private** banks to help treat illnesses and further research in the field;

Amendment

15. Underlines the importance of mothers donating cord blood and tissue at birth **especially** into public banks to help treat illnesses and further research in the field;

Or. en

Amendment 64

Marina Yannakoudakis, Frédérique Ries

Motion for a resolution

Paragraph 15

Motion for a resolution

15. Underlines the importance of mothers donating cord blood and tissue at birth either into public or private banks to help treat illnesses and further research in the field;

Amendment

15. Underlines the importance of mothers donating cord blood and tissue at birth either into public or private banks, **which adhere to common operational and ethical standards, to** help treat illnesses and further research in the field;

Or. en

Amendment 65

Margrete Auken

Motion for a resolution

Paragraph 15

Motion for a resolution

15. Underlines the importance of mothers **donating** cord blood **and tissue** at birth **either into** public **or private** banks to help treat illnesses and further research in the

Amendment

15. Underlines the importance of **encouraging** mothers **to donate** cord blood at birth **to** public banks to help treat illnesses and further research in the field;

field;

Or. en

Amendment 66

Marisa Matias

Motion for a resolution

Paragraph 15

Motion for a resolution

15. Underlines the importance of mothers donating cord blood and tissue at birth **either** into public **or private** banks to help treat illnesses and further research in the field;

Amendment

15. Underlines the importance of mothers donating cord blood and tissue at birth into public banks to help treat illnesses and further research in the field; **these banks must adhere to ethical standards and be regulated at European level in order to facilitate the implementation of a precautionary approach while traceability must be one of the conditions required for the authorisation of these banks at national or European level; emphasises that the allocation process through such banks must be fair, equitable, non-discriminatory and transparent;**

Or. en

Amendment 67

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Paragraph 15

Motion for a resolution

15. Underlines the importance of mothers donating cord blood and tissue at birth either into public or private banks to help treat illnesses and further research in the field;

Amendment

15. Underlines the importance of mothers donating cord blood and tissue at birth either into public or private **non-profit-making** banks to help treat illnesses and further research in the field;

Or. fr

Amendment 68
Marisa Matias

Motion for a resolution
Paragraph 15 a (new)

Motion for a resolution

Amendment

15a. Public cell banks must take the necessary steps to protect confidentiality of the data in order to reconcile the traceability requirement and the need to protect the donor's rights, such as medical confidentiality and privacy;

Or. en

Amendment 69
Andres Perello Rodriguez, Pilar Ayuso

Motion for a resolution
Paragraph 15 b (new)

Motion for a resolution

Amendment

15b. Donations of non-family allogeneic UCB — regardless of whether the bank is public or private — should be further developed, so that stored units of UCB are registered in the BMDW and available to any compatible patient who needs them;

Or. es

Amendment 70
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 15 c (new)

Motion for a resolution

Amendment

15c. Points out that this donation must be subject to consent from the mother that is free, informed and given in writing, and that this consent may be withdrawn at any time prior to the donation, with no particular requirement as to format;

Or. fr

Amendment 71
Esther de Lange

Motion for a resolution
Paragraph 15 d (new)

Motion for a resolution

Amendment

15d. Regrets that at the moment stem cells from umbilical cord blood are only stored at 1% of total births in the European Union;

Or. en

Amendment 72

Peter Liese, Marina Yannakoudakis, Miroslav Mikolášik, Alojz Peterle, Richard Seeber, Elena Oana Antonescu, Boguslaw Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution
Paragraph 16

Motion for a resolution

Amendment

16. Calls on Member States to raise awareness of public ***and private*** cord blood banking through information campaigns that may take place, for example, during ***antenatal*** classes;

16. Calls on Member States to raise awareness of public cord blood banking through information campaigns that may take place, for example, during ***prenatal*** classes ***but at the same times not exclude the activities of public cordblood banks including appropriately regulated***

*information campaigns by those private
cordblood banks.*

Or. en

Amendment 73
Marina Yannakoudakis, Frédérique Ries

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on Member States to raise awareness of public and private cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Amendment

16. Calls on Member States to raise awareness of public and private cord blood banking through information campaigns that may take place, for example, during antenatal classes; ***stresses that objective information should be provided about the advantages and disadvantages of cord blood banks, and in the case of autologous cord blood banks, the promotion material provided to families must be accurate;***

Or. en

Amendment 74
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on Member States to raise awareness of public and private cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Amendment

16. Calls on Member States to raise awareness of ***the existence and value of*** public and private ***non-profit-making*** cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Or. fr

Amendment 75
Margrete Auken

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on Member States to raise awareness of public **and private** cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Amendment

16. Calls on Member States to raise awareness of public cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Or. en

Amendment 76
Esther de Lange

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on Member States to raise awareness of public and private cord blood banking through information campaigns that may take place, for example, during antenatal classes;

Amendment

16. Calls on Member States to raise awareness of public and private cord blood banking through information campaigns that may take place, for example, during antenatal classes, **and that reflect all existing options related to babies' cord blood at birth i.e.: public donation, private storage, donation for research or discard.**

Or. en

Amendment 77
Françoise Grossetête

Motion for a resolution
Paragraph 16 a (new)

Motion for a resolution

Amendment

16a. Proposes that, in compliance with the provisions of the Charter of Fundamental Rights of the European Union, the information campaigns should ensure that parents have an informed choice about the various options relating to the use of the baby's cord blood;

Or. fr

Amendment 78
Frédérique Ries

Motion for a resolution
Paragraph 16 b (new)

Motion for a resolution

Amendment

16b. Calls on Member States to ensure at the same time better protection of parents right to informed consent and freedom of choice regarding cord blood stem cell preservation practices;

Or. en

Amendment 79
Margrete Auken

Motion for a resolution
Paragraph 16 c (new)

Motion for a resolution

Amendment

16c. Considers that public authorities should not promote donations of cord blood to private banks, given that the benefits of autologous treatment are yet to be proven;

Or. en

Amendment 80
Margrete Auken

Motion for a resolution
Paragraph 16 d (new)

Motion for a resolution

Amendment

16d. Has serious doubts that private cord blood banks for potential autologous treatment comply with the Charta of Fundamental Rights, which prohibits making the human body and its parts as such a source of financial gain;

Or. en

Amendment 81
Margrete Auken

Motion for a resolution
Paragraph 17

Motion for a resolution

Amendment

17. Proposes that Member States consider adopting and enforcing ***common*** operational and ethical standards for ***both*** public and private cord blood banks, ***such as those proposed by non-profit organisations such as the International Netcord Foundation and the Foundation for the Accreditation of Cellular Therapy (FACT);***

17. Proposes that Member States consider adopting and enforcing operational and ethical standards for public and private cord blood banks ***that ensure inter alia respect*** for the ***principle of non-commercialisation of the human body and its parts and that ensure traceability;***

Or. en

Amendment 82
Marisa Matias

Motion for a resolution
Paragraph 17

Motion for a resolution

17. Proposes that Member States consider adopting and enforcing common operational and ethical standards for **both** public **and private** cord blood banks, such as those proposed by non-profit organisations such as the International Netcord Foundation and the Foundation for the Accreditation of Cellular Therapy (FACT);

Amendment

17. Proposes that Member States consider adopting and enforcing common operational and ethical standards for public cord blood banks, such as those proposed by non-profit organisations such as the International Netcord Foundation and the Foundation for the Accreditation of Cellular Therapy (FACT);

Or. en

Amendment 83

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Paragraph 17

Motion for a resolution

17. Proposes that Member States consider adopting and enforcing common operational and ethical standards for both public and private cord blood banks, such as those proposed by non-profit organisations such as the International Netcord Foundation and the Foundation for the Accreditation of Cellular Therapy (FACT);

Amendment

17. Proposes that Member States consider adopting and enforcing common operational and ethical standards for both public and private **non-profit-making** cord blood banks, such as those proposed by non-profit organisations such as the International Netcord Foundation and the Foundation for the Accreditation of Cellular Therapy (FACT);

Or. fr

Amendment 84

Dagmar Roth-Behrendt

Motion for a resolution

Paragraph 17 a (new)

Motion for a resolution

Amendment

17a. Expects all Member States to

establish at least one public stem cell database;

Or. de

Amendment 85
Daciana Octavia Sârbu

Motion for a resolution
Paragraph 17 b (new)

Motion for a resolution

Amendment

17b. Encourages the update of the opinion issued by the European Group on Ethics in Science and New Technologies in 2004 on "Ethical Aspects of Umbilical Cord Blood Banking" (Opinion N° 19) in light of developments in cord blood stem cell preservation and ongoing clinical trials on the use of umbilical cord blood stem cells;

Or. en

Amendment 86
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 17 c (new)

Motion for a resolution

Amendment

17c. Calls on Member States to provide a territorial network of maternity centres authorised to carry out this procurement to guarantee cord blood supply in all population centres;

Or. fr

Amendment 87
Esther de Lange

Motion for a resolution
Paragraph 17 d (new)

Motion for a resolution

Amendment

17d. Encourages that all banks that respect the EU operational standards for collection and storage of cord blood are consulted by national authorities when defining and implementing national information campaign strategies towards parents.

Or. en

Amendment 88
Dagmar Roth-Behrendt

Motion for a resolution
Paragraph 17 e (new)

Motion for a resolution

Amendment

17e. Calls for European standards and requirements for private stem cell databases;

Or. de

Amendment 89
Philippe Juvin, Françoise Grossetête

Motion for a resolution
Paragraph 17 f (new)

Motion for a resolution

Amendment

17f. Highlights the legal and ethical questions raised by the autologous use of cord blood cells, namely the storage by banks of cord blood cells from newborn

babies in exchange for payment, with a view to later therapeutic use on the child in the event of an illness; calls, therefore, for a ban on all autologous donation;

Or. fr

Amendment 90

Marina Yannakoudakis, Frédérique Ries

Motion for a resolution

Paragraph 18

Motion for a resolution

18. *Encourages* public and private cord blood banks to collaborate more closely in order to increase the availability of national cord blood and tissue samples;

Amendment

18. *Notes that collaboration models and opportunities between* public and private sectors *already exist in some Member States, and encourages public and private* cord blood banks to collaborate more closely *with regard to the principle of subsidiarity*, in order to increase the availability of national cord blood and tissue samples *and therefore maximum patient benefit*;

Or. en

Amendment 91

Philippe Juvin, Françoise Grossetête

Motion for a resolution

Paragraph 18

Motion for a resolution

18. Encourages *public and private* cord blood banks to collaborate more closely in order to increase the availability of national cord blood and tissue samples;

Amendment

18. Encourages *Member States'* cord blood banks to collaborate more closely in order to increase the availability *and exchange* of national, *European and international* cord blood and tissue samples;

Or. fr

Amendment 92
Marisa Matias

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Encourages public and *private* cord blood banks to collaborate more closely in order to increase the availability of *national* cord blood and tissue samples;

Amendment

18. Encourages public *human tissue* and cord blood banks to collaborate more closely in order to increase the availability of cord blood and tissue samples *at national and European level*;

Or. en

Amendment 93
Margrete Auken

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Encourages public *and private* cord blood banks to collaborate more closely in order to increase the availability of national cord blood and tissue samples;

Amendment

18. Encourages public cord blood banks to collaborate more closely in order to increase the availability of national cord blood and tissue samples;

Or. en

Amendment 94
Esther de Lange

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Encourages public and private cord blood banks to collaborate more closely in order to increase the availability of

Amendment

18. Encourages public and private cord blood banks to collaborate more closely in order to increase the availability of cord

national cord blood and tissue samples;

blood and tissue samples *at national and European level*;

Or. en

Amendment 95

Andres Perello Rodriguez, Pilar Ayuso

Motion for a resolution

Paragraph 20

Motion for a resolution

Amendment

20. Calls on Member States to consider expanding the number of centres for collection of blood stem cell samples in order to increase the chances of finding a matching donor for those in need of a transplant;

deleted

Or. es

Amendment 96

Andres Perello Rodriguez, Pilar Ayuso

Motion for a resolution

Paragraph 20 a (new)

Motion for a resolution

Amendment

20a. Member States will consider increasing the number of donors of bone marrow and peripheral blood stem cells, improving their registries of bone marrow donors so that, with the collaboration of the national registries of the other countries, through the BMDW any patient in need of a stem cell transplant has the best chance of finding a compatible donor;

Or. es

Amendment 97

Peter Liese, Marina Yannakoudakis, Margrete Auken, Miroslav Mikolášik, Richard Seeber, Elena Oana Antonescu, Elisabetta Gardini, Boguslaw Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Paragraph 22

Motion for a resolution

22. *Stresses* that in *order* to *guarantee* respect *for* the *existing regulatory diversity across Member States which reflects differing national values and practices* in this *field*, the *scope* of *this report* does *not include issues surrounding embryonic stem cell research, therapeutic cloning and in-vitro fertilisation;*

Amendment

22. *Underlines* that *it is Member States competence to allow, prohibit or regulate research with human embryonic stem cells and in vitro fertilisation but that Member States in this respect need* to respect the *rules set out in the Directive 2004/23 including the quality and safety and the principal of unpaid donation. Points out that the European Union has limited competence in this area and needs to respect when applying this competence the principles of the charter of fundamental rights and the principles applied in the judgement of the European Court of Justice.*

Or. en

Amendment 98

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Richard Seeber, Elena Oana Antonescu, Elisabetta Gardini, Boguslaw Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Paragraph 23

Motion for a resolution

23. Calls on the Commission to *consider revising the principles governing tissue and cell donation as laid down in* Directive 2004/23/EC, in order to bring them into line with the principles governing organ donation laid down in Directive 2010/45/EU, and to take account of scientific developments and the

Amendment

23. Calls on the Commission to *propose as soon as possible a revision of* the Directive 2004/23/EC in order to bring them into line with the principles governing organ donation laid down in Directive 2010/45/EU, and to take *into* account *the new legal situation after the entering into force of the Lisbon Treaty and to take into*

recommendations of this report;

account the scientific developments, the practical experience of actors in the sector and the recommendations of this report

Or. en

Amendment 99

Peter Liese, Margrete Auken, Miroslav Mikolášik, Alojz Peterle, Richard Seeber, Elena Oana Antonescu, Elisabetta Gardini, Bogusław Sonik, Paolo Bartolozzi, Jolanta Emilia Hibner, Renate Sommer, Anna Záborská

Motion for a resolution

Paragraph 23 a (new)

Motion for a resolution

Amendment

23a. Asks the Commission to also propose a revision of Regulation EC 1394/2007 in order to include provision that guarantees the application of the principle of unpaid donation similar to the Directive 2010/45 and to take into account the problems in the implementation of the regulation especially for SMEs.

Or. en