## German Bundestag

## Study Commission on Law and Ethics in Modern Medicine

## Summary report

### Supplement to the interim report on stem cell research focussing on importation problems

# Research in imported human embryonic stem cells

## 0 Preliminary remarks

An intensive debate is currently under way, not only in Germany, on the subject of research in embryos and human stem cells. A stream of new information in the biomedical field is feeding hopes for of new therapeutic approaches in the long term for diseases that are at present untreatable. Research with all forms of stem cells is also being conducted in an attempt to gain a deeper understanding of the development of cells, tissues and organs.

Some forms of stem cell research, however, are approaching the ethical and legal boundaries. Legislators must decide whether research should in future be permitted in Germany using human embryonic stem cells imported from other countries. The German Bundestag (BT) considered the question of research in imported pluripotent human embryonic stem cells on 7 July 2001 (BT publication 14/6551). The German Bundestag will be addressing this topic again in connection with the forthcoming decision by the German Research Association on an application for research involving the importation of human embryonic stem cells.

The Study Commission on law and ethics in modern medicine, set up by the German Bundestag on 24 March 2000, takes the view that the question of importing human embryonic stem cells cannot be considered in isolation from the overall context of stem cell research. The Commission is therefore submitting its interim report at this point, since it gives a comprehensive overview of the current scientific and medical status of stem cell research and presents the legal and ethical lines of argument, highlighting the options for regulation and its recommendations on this subject. The intention is to contribute to informed debate in the German Bundestag and also in the public domain.

This summary focuses on the problems of importing human embryonic stem cell lines into Germany, a matter also comprehensively assessed from the ethical and legal viewpoints in the Interim Report.

## 1 Terminology

Stem cells are cells that are capable of reproducing themselves by cell division; both they themselves and their daughter cells are able to develop into cells with a variety of specialisations (differentiation). They are therefore particularly suitable for cell and tissue replacement.

With respect to their potential for developing into a variety of tissue cells, a distinction is drawn between totipotent, pluripotent and organ-specific stem cells:

- **Totipotency**: Totipotent cells are those capable of forming a complete organism. The fertilised egg cell (zygote) and the first cells developing from it by cell division, presumably up to the 8-cell stage, are totipotent. One human totipotent cell, after transfer into the uterus of a woman, can develop into a complete individual human being. Under the terms of § 8 of the Embryo Protection Act, totipotent cells are equivalent to embryos.
- **Pluripotency**: Pluripotent cells are those capable of differentiating into many types of tissue but no longer capable of developing into a complete organism. Embryonic stem cells (ES cells) or embryonic germ cells (EG cells) are examples of pluripotent cells.
- **Tissue-specific adult stem cells**: the role of adult stem cells in the adult organism is to regenerate specific types of tissue. Recent research findings show that adult stem cells possess an extraordinarily high degree of plasticity, i.e. under certain conditions they are capable of developing into different types of tissue.

Depending on their origin and method of derivation, a distinction is made between:

- embryonic stem cells (ES cells) from embryos derived from in-vitro fertilisation (IVF);
- embryonic stem cells produced by cell nuclear transfer (key words "therapeutic clones", "Dolly technique");
- neonatal stem cells from umbilical cord blood;
- embryonic germ cells (EG cells) from aborted fetuses;
- tissue-specific adult stem cells (AS cells).

Detailed description and discussion of the above cell types, their derivations and the questions of ethical assessment and legal regulation are presented in the interim report on stem cell research.

## 2 Legal situation

The importation of totipotent cells for research purposes is regulated by the Embryo Protection Act (ESchG). Totipotent cells, under the terms of § 8 para. 1 of the Embryo Protection Act, are equivalent to embryos. To import totipotent cells is therefore to import embryos. The acquisition and use of embryos for a purpose other than preserving their life is prohibited and therefore constitutes a punishable offence under the Embryo Protection Act (§ 2 para. 1 ESchG). The acquisition, including importation from other countries, and the harvesting of embryonic stem cells from human embryos for use in embryonic stem cell research is therefore not possible in Germany.

The situation relating to the importation of pluripotent embryonic stem cells is different. Although pluripotent embryonic stem cells are derived from embryos or totipotent cells, they are neither embryos nor totipotent cells, since they can no longer develop into human beings. The importation and acquisition of pluripotent stem cells and research in these cells is therefore permissible under the Embryo Protection Act.

Under German law, however, the importation of pluripotent stem cells from another country is legally permitted only if the importers in the legal sense are acting neither as instigators nor as assistants to those who are producing embryonic stem cells in that country. Importation therefore presents no legal problems if it is ensured that no connection exists between the order or request for embryonic stem cells and their derivation from embryos. This is the case where the stem cells were already available as cultures at the time of initiation of the contractual agreement relating to importation and where the method, circumstances and time of derivation are also fully documented. In particular, financial, technical or personal assistance in the manufacture of embryonic stem cells in the other country is therefore excluded.

There is no legal distinction between the importation of pluripotent stem cells derived from embryos from in-vitro fertilisation or from egg cells donated for research purposes and the importation of pluripotent stem cells obtained by the use of totipotent cells created with the use of cloning techniques. Even pluripotent cells produced by means of the creation of chimeras and hybrids, which is prohibited under the Embryo Protection Act, can be imported. The importation of pluripotent stem cells derived by means of a method not prohibited by the Embryo Protection Act, for example from primordial germ cells from aborted fetuses or by the reprogramming of human somatic stem cells, is also permitted.

Apart from the Embryo Protection Act and the general regulations of the Criminal Code relating to participation in criminal acts, there is currently no other legislation or official regulation that limits the importation of pluripotent human embryonic stem cells. Nor are there

any regulations at EU level that limit importation into the EU or from other EU states into Germany. Nor are any national export restrictions known in relation to countries outside the EU which might export such cells, such as Australia, Israel and the USA. However, often far-reaching restrictions do exist under the law of contract and patent law.

## 3 Ethical and constitutional assessment of stem cell research

As discussed in detail in the Interim Report, research may relate to stem cells derived from adult organisms (AS cells), from aborted fetuses (EG cells), from cord blood or from the blastocyst stage of embryos (ES cells).

Particular ethical problems are raised by stem cell research in which the stem cells are derived from human embryos (ES cells). In live embryos, according to the current state of knowledge, such derivation leads to the death of the embryo concerned or at least its unsuitability for implantation into the uterus. This would invariably be the case where embryonic stem cells are harvested from embryos at the blastocyst stage.

The starting point for solution of the ethical problems is definition of the moral status of the human embryo in vitro and the claims to protection arising from this. In Germany - and throughout the world - various views are held on this matter. The fundamental question is whether the human being acquires human dignity and warrants unlimited protection from the start of its development - on completion of fusion of the nuclei - or whether, and to what extent, this status depends on its degree of development. Ethical positions on the moral status of the embryo are discussed in detail in the Interim Report.

A fundamental factor in clarifying under constitutional law whether it is permissible to derive stem cells from embryos is the question of the point at which human life begins to enjoy the right of protection of human dignity in accordance with article 1 para. 1 of German Basic Law and the right to life under article 2 para. 2 of German Basic Law. Views on this subject vary widely. At one end of the scale lies the assumption that, on completion of fertilisation, a living human being exists that enjoys the same inviolable protection of human dignity as that enjoyed by an individual at birth. Then comes the assumption of the protection of life – which may be balanced against other rights - with protection of the human dignity of the embryo arising at a later stage. At the other end of the scale is the view that a living human being acquires the status of a person and the associated specific rights to protection under Basic Law only at birth or even later, once certain characteristics have been acquired. Further views lie between the positions outlined here. The last view mentioned will not be taken into account in the following discussion, since it is not supported by constitutional law and is therefore not an option in the legislative decision-making process.

Irrespective of differences concerning the extent of protection of human dignity and the possibility of balancing the right to life, the Study Commission was unanimous in its view that the embryo from fusion of the nuclei onwards, and therefore the embryo in vitro, as a human life in its earliest form enjoys the protection of basic rights. Those who see the act of deriving embryonic stem cells from human embryos as a violation of human dignity conclude that this practice is inadmissible, as do those who base their views on the protection of life rather than human dignity but who allow, in view of the high-ranking value of life as protected by law, only the weighing of life against other life. However, those who also argue from the principle of protecting life, but consider it admissible to weigh the protection of the life of the embryo with other high priority rights, would allow greater latitude in this balancing process.

Even in establishing the above positions – in the light of the exceptional value given to life within the German constitutional order – an essential prerequisite for limitation of the right to life of the embryo for research purposes would be the explicit demonstration that this is appropriate, necessary and proportionate with respect to the intended objective. Research involving the use of embryos must therefore answer the following questions:

- Can ethically less controversial means be selected for high priority medical research?
- In particular, would research in animal cells represent such an alternative?
- Is research in adult stem cells or stem cells from EG cells derived from aborted fetuses or umbilical cord blood feasible?
- Is the research using embryos necessary at this time?

The Study Commission is of the view that, in the light of the outstanding questions concerning appropriateness, necessity and proportionality raised in the interim report on stem cell research, the ethical and constitutional aspects mentioned and the rule that ethically less controversial methods are preferable to the more controversial, legal approval of the derivation of stem cells from embryos cannot be recommended, even where these are "supernumerary".

## 4 Ethical assessment of the importation of embryonic stem cells

The current situation in Germany, in which research in embryonic stem cells is made possible by importing pluripotent stem cells from other countries, has raised feelings of alienation and rejection in some sections of society. The attempt to uphold a ban on the derivation of such cells, as defined by the Embryo Protection Act, without renouncing the fruits of research in these cells is clearly regarded not only as a legal contradiction in values but also as an ethically dubious case of "double standards". The underlying ethical feeling here is that no discrepancy should exist between an awareness of standards and the regulation of actions, and that exploitation of the options existing in law cannot be divorced from the question of ethical

justification. There can be no disagreement with this underlying intuitive realisation, but it requires distinctions to be drawn with regard to ethical evaluation of the potential importation permitted by law.

To the extent that the stem cell lines to be imported for research purposes, as described above, are pluripotent and are therefore not embryos, the ethical and legal problems relate not to the object of the research made possible by such imports, but to the origin or derivation of these stem cell lines from embryos, whether from embryos created from that specific purpose, from embryos produced by cell nuclear transfer ("therapeutic" cloning) or from "supernumerary" embryos.

In the Interim Report of the Study Commission on "Law and Ethics in Modern Medicine", the diverse views on the ethical evaluation of importation are presented in detail as follows:

The weight of the ethical objections raised to importation of such stem cell lines depends on the ethical assessment of these methods of derivation. According to the positions outlined above with regard to the moral status of the embryo in vitro and its consequent worthiness of protection, importation of stem cell lines from embryos created purposely or derived from cell nuclear transfer would be possible without ethical objection only from the perspective of a position that regarded the worthiness of protection of the embryo in vitro as *non-existent*, or clearly reduced.

If one assumes that worthiness of protection is not reduced and that the use of "supernumerary" embryos constitutes a violation of human dignity and therefore that such use cannot be considered even for priority objectives, correspondingly strict reservations apply to the importation of stem cell lines from "supernumerary" embryos. If the view is held that the use of "supernumerary" embryos is not a violation of human dignity as such and that intervention in the right to life of these embryos is potentially justified under certain conditions in view of other priority objectives, then a similar assessment also applies to the importation of stem cell lines derived by this method in other countries. The same applies to the position based on a diminished worthiness of protection for the embryo.

Even for the position that regards the harvesting of stem cells from "supernumerary" embryos as ethically unjustifiable, some differentiation is necessary between the method of derivation and the act of using the stem cell lines, with regard to the weight of the ethical problem. Also of importance is the question of whether such use relates to existing stem cell lines or whether it gives rise to the derivation of additional stem cell lines and therefore to the destruction of further "supernumerary" embryos.

If the balancing of the right to life for "supernumerary" embryos with other objectives and values is regarded as ethically justifiable, these must be of particularly high priority.

Possible high priorities might be: the gaining of directly therapeutically useful information, the gaining of indirectly therapeutically useful information and the gaining of basic knowledge, in particular concerning development of the human individual, especially at molecular level and to the understanding of the programming, reprogramming and transdifferentiation processes in embryonic and adult human stem cells.

The level of priority of these objectives may vary in kind, therapeutic relevance being the decisive factor.

If an ethical balancing process of the kind described is held to be legitimate, the criterion applies analogously to the importation of human embryonic stem cells, that ethically less controversial methods are preferable to the more controversial and that the lack of alternatives to the controversial means must be established before entering upon the process of weighing ethical considerations with regard to priority objectives.

Unanimously regarded as not ethically legitimate is the importation of embryonic human stem cell lines derived from *stem cells produced specifically for that purpose or created by cell nuclear transfer*. Since the method of derivation, from the standpoint of undiminished protection of human embryos, must be seen as a violation of human dignity and even from the standpoint of reduced protection as a mode of action that contravenes the worthiness of the embryo to be protected, the importation of stem cell lines derived by such a method must also be regarded as ethically dubious, particularly since the appropriateness of and need for these methods of derivation are dubious.

With respect to the importation of stem cells derived from "supernumerary" embryos, approval *without limitation* is ethically justifiable only if the derivation of stem cells *from "supernumerary" embryos* for priority purposes is also accepted in principle. Those who hold this view, if they are to be consistent, must consider a change in the legislation.

If the derivation of stem cells from "supernumerary" embryos is regarded as justifiable, however, on the basis of a balancing process roughly in accordance with the above criteria, the importation of stem cell lines obtained from these can only be approved if it is appropriate and necessary *in specific individual cases* in order to attain objectives of a priority that makes the importation appear to be proportionate. This applies in particular where importation is for research needed only as an intermediate stage, intended to obviate the need to derive such cells from human embryos in future, and where it is limited exclusively to stem cell lines already in existence.

If all derivation of stem cells from "supernumerary" embryos is regarded as ethically unjustifiable since it violates human dignity, approval of the importation of such stem cell lines is also a contradiction in ethical values. However, from this standpoint, the question arises as to

how the existing legal situation is to be handled. If in fact it is assumed that there is not to be a general legal prohibition, from the standpoint described above it would be appropriate to consider linking the current legal permissibility of importation to specific individual cases and strictly defined licensing conditions, as the lesser evil. This does not alter the fact that, from this standpoint, the legality of research in imported embryonic stem cell lines does not absolve the individual researcher of ethical responsibility.

Criteria such as promoting Germany as a research location and the consideration of economic aims must be regarded as clearly of secondary importance to the above criteria such as the worthiness of the human embryo to be protected on the one hand and the priority objectives of treatment and research on the other.

## 5 Regulatory alternatives

### a) Prohibition of the importation of ES cells

Research in imported embryonic stem cells is covered by the freedom of research guaranteed under German Basic Law. Article 5 para. 3 of Basic Law ("Art and science, research and teaching are free.") is not subject to limitation or qualification by statute. But even basic laws guaranteed without reservation are subject to limitations in their implementation, though such limitations must arise directly from the constitution itself:

In the matter of prohibition of the use of embryos for a purpose not directly contributing to preserving their life and in the prohibition of cloning (cf. §§ 2 and 6 ESchG) if it is clearly a question of the rights of third parties (the protection of incipient life under Art. 2 para. 2 or Art. 1 of Basic Law) conflicting with Art. 5 para. 3 of Basic Law, then, in the case of the importation of already established pluripotent embryonic stem cells, no basic rights conflict directly with the basic right in Art. 5 para. 3 of Basic Law, since the decision relating to the life and death of the embryo has already been taken here prior to importation and a human individual cannot develop from pluripotent stem cells. Pluripotent stem cells do not enjoy the status to which basic rights are ascribed.

In addition to conflicting basic rights, however, other legal values of constitutional importance may be taken into account in restricting freedom of research. The fundamental value judgement of the constitution in favour of life and human dignity is called into question. This value judgement may be affected by the approval of importation, because many take the view that the use of stem cells also condones the method of their derivation and it is further feared that human dignity and the right to life, as protected by the constitution, could be jeopardised directly if importation should lead to a demand for the production of new stem cell lines. Examination of such obvious risks is part of an assessment of consequences that the legislator is

obliged to undertake, on the basis of the State duty of protection arising from Articles 1 and 2 of Basic Law. The Federal constitutional court, for example, regarded the limitation of the freedom of science and research in the form of the Animal Protection Act as justified without conflicting with Basic Law, in view of the shared responsibility of human beings for other creatures.

The extent to which a general ban on the importation of human embryonic stem cells would be compatible with European law is also unclear. Introduction of a ruling on importation agreed within the EU and valid throughout the EU is under discussion.

In this context, the degree to which a general import ban could be regulated by law is difficult to decide. A definitive estimation by the Study Commission of the leeway available under constitutional law is therefore impossible. The legislator is the primary interpreter of the constitution and has to determine by law the boundaries that can and should be drawn under constitutional law. The deliberations of the Study Commission therefore concentrate on the ethical questions on which the legislator's assessment is also based.

### b) General approval of the importation of ES cells

This position within the range of opinions is adopted only by advocates of that view of the status of the embryo described in the section of the Interim Report concerning the moral status of the embryo as the "radical gradualist position".

### c) Limitation of importation

A third option that may be considered is the attachment of strict conditions to the permissibility of importation. These conditions may link the permissibility of importation to certain criteria, e.g. allowing the importation of ES cells only where it is demonstrated that their use in the individual case in question is appropriate, necessary and proportionate.

Conditions for the importation of ES cells can also be linked to the origin and circumstances of derivation of the embryonic stem cells. It would be possible, for example, to restrict importation to those stem cell lines derived from cryopreserved "supernumerary" and permanently orphaned embryos, with further additional conditions being satisfied regarding their derivation. These conditions relate, amongst other things, to the voluntary consent of the donor couple, given after being informed of the nature and purpose of the research and its potential commercial exploitation (qualified informed consent), and the assurance that commercial interests were excluded, both on the part of the doctors and researchers involved and also on the part of the donor couple, in the derivation process and in the declaration of consent. In view of the ethical need to avoid the risk of destroying further embryos as a result of import-

ing embryonic stem cells, an arrangement might be considered in particular which allows only the importation of those embryonic stem cell lines established, in accordance with the decision of the US President, prior to 9 August 2001, the date of this decision, and included in a register drawn up by the NIH[1].

Regulation of importation along these lines would have to be put in place by the legal introduction of a requirement for import approval, such approval being conditional on the fulfilment of the legal preconditions.

In principle, the same questions arise here in relation to the limitation of freedom of research as arise with respect to a general import ban. The legislator must decide to what extent the permissibility of research in imported embryonic stem cells in favour of other constitutional values is to be linked to specific preconditions for approval.

## 6 Regulatory options and recommendations on research in imported ES cells

Maintaining the present legal situation in the area of protection of the embryo, the decision must be taken as to whether, while observing the basic right of the freedom of science and research

- separate assessment of the legal and ethical aspects of the derivation and importation of human embryonic stem cells is possible or
- legal and ethical aspects of derivation and importation must be assessed together.

Under criminal law, the importation of pluripotent embryonic stem cells is not limited at present if the intention to import does not lead to punishable involvement in their derivation. This applies both to the use of imported embryonic stem cells for research purposes and also to any possible future therapeutic use. No statement is made, however, concerning the conformity of importation with the spirit of the Embryo Protection Act.

Debatable points, however, are

- whether toleration of regulated importation of existing human embryonic stem cell lines can prevent the killing of further embryos, since research in existing human embryonic stem cell lines is sufficient to obtain new information or

[1] The cell lines must satisfy the following criteria if they are to be used in research involving US public funds:
- derivation of the cells was initiated before 9 August 2001,
- informed consent has been obtained from the couple from whom the embryo originated,
- the cells are derived from an embryo created for reproductive purposes but which can no longer be used for that purpose (known as a "supernumerary" embryo),
- there was no financial inducement to make the embryo available for research.

- whether toleration of importation does not also imply toleration of the method of derivation, since research with embryonic stem cells cannot be separated from their derivation and
- whether the production of new stem cell lines and the killing of further embryos is not set in motion if demand increases and if it should emerge that existing stem cell lines are neither quantitatively nor qualitatively adequate and
- whether this research, should therapeutic benefit seem possible, will lead to "therapeutic" cloning.

For the first of these points, a regulatory system of approval is discussed, linking the approval of importation with a mandatory demonstration of appropriateness, necessity and proportionality and preventing extension to new stem cell lines, and requiring the following conditions to be satisfied:

- Restriction to embryonic stem cell lines created prior to a certain deadline (in accordance with the list drawn up by President George W. Bush);
- Restriction of use to research for priority purposes that cannot be achieved by other research. The general priority criteria would have to be established by the legislator, since the concept of protection of life would also be valid here;
- Coupling to the demonstration that the stem cells have been derived only from those embryos not created especially for stem cell harvesting but were cryopreserved for the purposes of IVF treatment and were "supernumerary" or permanently orphaned and that the genetic "parents" have given their consent after having received full information about the purpose of the research and other relevant information.
- Linking to quality assurance and monitoring criteria;
- Documentation and publication requirements;
- Prohibition of commercialisation.

Legally, the requirement for approval of this kind would constitute acceptable regulation of the research activity in terms of establishing a safe balance between the freedom of research and the necessary avoidance of jeopardising fundamental values protected by the constitution, such as human dignity and the right to life.

Regulation of the conditions under which importation is permitted should not, as for example in the USA, draw a distinction between public and private research. In other words, the conditions under which importation is permitted are to be regulated by law. Only then are they

binding for private sector research. A further requirement would be a transparent control authority legitimised by the State.

For advocates of the view that considers it possible in relation to human embryos in vitro to balance the protection of life while respecting human dignity, importation can be approved if the imported stem cell lines are derived from "supernumerary" embryos and if they were derived with the informed consent of the parents. This applies in particular where importation is limited strictly to existing stem cell lines. Such approval, in addition to fulfilment of the criteria mentioned above, does also require demonstration of the high priority of the research objectives and the lack of alternatives to the research methods used to achieve these objectives. The dilemma arising as a result of importation, involving exploitation of the killing of embryos tolerated abroad though prohibited in this country, is acceptable to advocates of this position only if the appropriateness, necessity and proportionality of such importation and research into embryonic stem cell lines can be demonstrated.

If one proceeds from the gradualist position of reduced worthiness of protection for the human embryo, the importation of human ES cell lines is ethically legitimate. Here again, however, a suitable balance must be found between the existing worthiness of protection of the embryo recognised by this view and the high priority of the research objectives; moreover, the appropriateness, necessity and proportionality of importation must be demonstrated.

Ethically, the importation of stem cell lines derived from human embryos cannot be reconciled with the position that from the outset the human embryo is entitled to human dignity and therefore deserves unlimited protection. The Embryo Protection Act also proceeds from this view. In this context, examination of the conditions for a legally binding import ban should be attempted. It is difficult ethically to draw a distinction between criteria for the protection of embryos outside Germany and those within Germany. Irrespective of the fact that it is legally possible to assess derivation separately from importation, such separate ethical evaluation carries the risk of destabilising the legitimation of embryo protection.

Some of the members of the Study Commission are of the opinion that both the German Bundestag as the legislator and the Federal government as the executive should use and implement all available opportunities to combat the killing of embryos, including an import ban. These members hold the view that it is impossible to prevent the killing of further embryos by means of import regulation limited to the existing stem cell lines and other restrictive criteria. Such a regulation would in fact not only place Germany among the potential users of existing stem cell lines but would also help to give impetus to the demands already detected in the scientific community for better quality stem cell lines and for the derivation of stem cell lines within Germany itself. Importation would create a demand that would induce and legitimise a

corresponding supply, leading to the destruction of further human embryos. However, since in the view of all those advocating the above position a ban should be retained on the use by third parties of human embryos, the importation of cell lines arising from behaviour that should be banned, to maintain consistency, should also not be tolerated.

Should the banning of importation based on the protection of dignity and life not prove feasible, other advocates of an import ban might find tolerable a closely regulated import arrangement under the strict licensing conditions mentioned above, in the context of an ethical evaluation which sees this as the lesser evil ("minus malum" assessment). An important argument here is the view that the killing of further embryos would be prevented by restriction by law to the existing stem cell lines. This applies in particular where importation is for the purposes of research required only as an interim stage, which makes the future derivation of such cells from human embryos unnecessary and is itself already restricted to existing stem cell lines. The legislator has the opportunity, by clearly restricting legally permitted imports to existing cell lines, to suppress a demand for additional cell lines and remove the inducement to kill further embryos for importation. It would be necessary to ensure that this would not give rise to any change in the Embryo Protection Act with a view to conditional approval of the production of stem cell lines within Germany which would then make use of the import criteria previously introduced.

Regulatory alternatives

The German Bundestag Study Commission on law and ethics in modern medicine, in view of the ethical conflicts, continues to regard the derivation of stem cells from embryos involving the destruction of human life as unjustifiable. Members are unanimous that the killing of embryos for research purposes must be prevented. The Study Commission is in favour of maintaining the high level of protection provided by the Embryo Protection Act.

On the question of the importation of human embryonic stem cells for research purposes, two lines of argument exist within the Study Commission.

Both positions share the view that the necessary regulations must apply equally to the public and to the private sector. They should therefore be placed on a legal footing.

Argument A:

The Study Commission, respecting all arguments, declares itself opposed to the importation of human embryonic stem cells. Its opinion is therefore that the German Bundestag and the Federal government should take all possible measures to prevent the importation of human embryonic stem cells.

The Study Commission regards the use of human embryos for research purposes, even if this takes place abroad, as ethically unjustifiable and scientifically not sufficiently well founded. The necessary basic research can be conducted adequately with stem cells of other origins (embryonic stem cells from primates, cord blood stem cells, adult stem cells, etc.), without opening the door to the misappropriation of human embryos.

Argument B:

Following the deliberations of the Study Commission it seems doubtful whether a complete ban on the importation of human embryonic stem cells derived from embryos abroad can be established on the basis of constitutional and European law. The importation of human embryonic stem cells is therefore to be tolerated under strict conditions. Adherence to these conditions is to be monitored by a State-authorised control body whose operations are open to scrutiny.

The necessary prerequisite to the permissibility of importation, in the view of the Study Commission, is in particular the following: restriction of imports to the currently existing embryonic stem cell lines derived from cryopreserved "supernumerary" embryos (specific deadline to be defined as in the "Bush regulation" of 9 August 2001); demonstration of the appropriateness, necessity and proportionality of the research project for which the import application is made; demonstration of qualified informed consent.

Under these strict licensing conditions within an ethical assessment, importation is tolerable, particularly since limiting the permissibility of importation to currently existing stem cell lines will prevent the killing of further embryos for research purposes.

This import regulation is to be linked to the guarantee of continuing protection of the embryo in Germany at its existing high level.

Argument A

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