

Briefing paper on the need to protect the future possibility of treating serious disease by therapies based on embryonic stem cells by giving the Human Fertilisation and Embryology Authority the power to licence such treatment.

Prepared by

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Context:

Human Fertilisation and Embryology Bill: Part 1-Amendments of the Human Fertilisation and Embryology Act 1990

Summary:

Therapies based on human embryonic stem (ES) cells have a great potential to cure a range of serious and debilitating diseases. The derivation of embryonic stem cells is currently permitted under research licence regulations by the HFEA. Whereas the new Bill continues to provide licenses can authorise the derivation of ES cells for research into curing serious disease, it does not allow licenses for actual use in therapy. This lack of provision is at odds with the expectations of the regulatory authorities and the research and patient community.

Unless this oversight is remedied, the Bill will allow ES cell derivation to develop cures for serious diseases but fail to permit the use of cures developed by that research.

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(2) Background to the Legislation

It is now widely known that embryonic stem cells harbour a potentially great therapeutic potential by virtue of being able to differentiate into almost any type.

Whenever embryonic stem cells are derived, they come from a very early embryo: the blastocyst which contains less than a hundred cells, some of which are embryonic stem cells.

Thus the derivation of ES cells remains squarely within the remit of the Human Fertilisation and Embryology Bill.

There has already been discussion as to how stem cell therapies will be regulated in the UK. In May 2007, the Human Fertilisation and Embryology Authority, the Human

Tissue Authority and the Medicines and Healthcare products Regulatory Agency published a joint statement on the regulation of stem cell therapies which stated as follows:

“Future stem cell research into potentially life-saving medical therapies is being safeguarded by new proposals from Government regulators. The aim is to ensure that the highest standards are met from their derivation in the laboratory through to their clinical application.

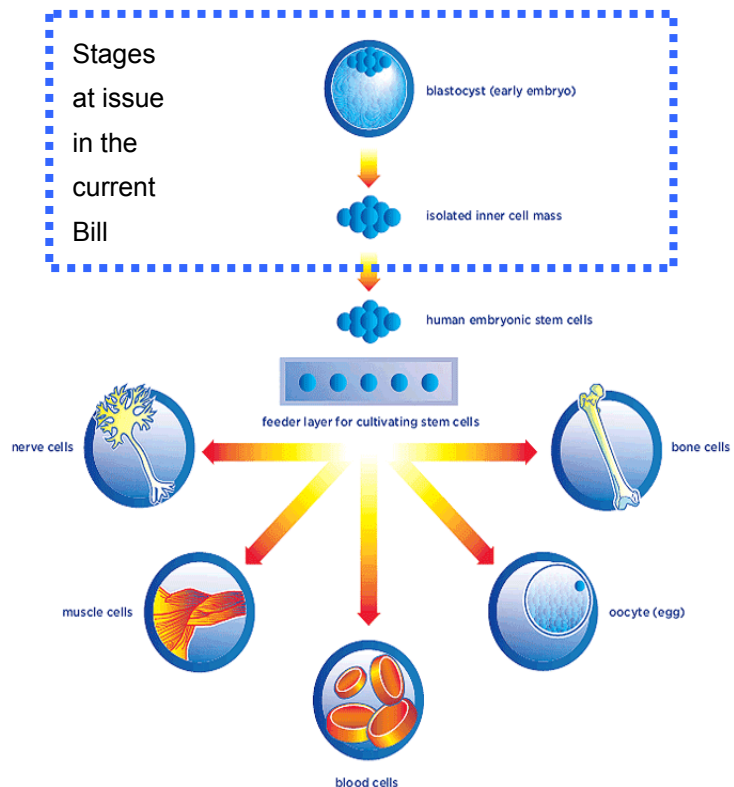
The Human Fertilisation and Embryology Authority is responsible for embryos and gametes, including the use of embryos in the derivation of cells, but not the stem cells themselves.

The next stage is the processing or derivation of stem cell lines from these embryonic stem cells in the laboratory; where they are fully characterised and cultured to ensure uniform characteristics.

The Human Tissue Authority will regulate the processing, storage and distribution of these stem cell lines for human application once the European Tissues and Cells Directive (EUTCD) comes fully into force.

During the processing/derivation phase, stem cells do not come within medicines regulation. However, once Master Cell Banks have been created with a reasonable expectation of clinical utility in a medicinal product, they fall within the remit of the Medicines and Healthcare products Regulatory Agency.”

The stem cell community has welcomed efforts to create a seamless web of good regulation that covers the entire trajectory of stem cell therapies. However, these plans may be rendered ineffective for some stem cell strategies by the current Bill:



(3) Looking at the new legislation

The 1990 Act makes no mention of using cells for treatment other than infertility.

On casual reading, this situation may appear differently in the new Bill:

- (1) The Authority may grant the following and no other licences—
- (a) licences under paragraph 1 of Schedule 2 to this Act authorizing activities in the course of providing **treatment services**,
 - (aa) licences under paragraph 1A of that Schedule authorising activities in the course of providing non-medical **fertility** services,
 - (b) licences under that Schedule authorising the storage of gametes, embryos or human admixed embryos, and
 - (c) licences under paragraph 3 of that Schedule authorising activities for the purposes of a project of **research**.

(section 11, our emphasis)

However, in the Bill "treatment services" means

"medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children"

(section 2(1))

In combination, this means that the bill still contains no provisions for treatment of any conditions other than infertility.

This may seem extremely odd considering that the Bill expressly allows and promotes embryology research with the purpose of

"developing treatments for serious disease or other serious medical conditions"

(Schedule 2 sec.3A (2-b))

This has the consequence, that when it comes to embryonic stem cell therapy, the Bill may allow research but have no powers to make the resulting treatment legal.

Embryonic stem cell therapies may become a more routine procedure within the lifetime of the new Act. Will it be necessary for doctors wishing to employ stem cell therapies to create research projects just to remain within the law? Increasingly this will become more difficult when patient or disease specific lines are generated under clinical conditions. In anticipation of the development of ES cell based therapies, the MRC is currently establishing stem cell derivation centres which comply with EU regulation on Good Manufacturing Practice in tissues and cell products. The new law should be consistent with the Governments intention to develop new stem cell therapies without delay.

If the issue of licenses for therapy is not addressed at this juncture an extensive revision of the law may be required in the near future.

In the Bill, this situation can only be remedied if

Section 11 and Schedule 2 are amended.

We sincerely hope that the honourable Members of Parliament will find a cross-party consensus on this important issue.

This information sheet is subject to an ongoing process of revision.

Please ensure you use only the most up-to-date version which can be obtained from www.nesci.ac.uk

This version expires on **Monday, June 2nd 2008**.

(4) Further information

This brief has aimed at presenting the perspective of scientists and clinicians on the proposed legislation in a succinct and simple manner.

We would greatly welcome a chance to explain the underlying science and the therapeutic potential in greater detail. Please do not hesitate to contact us with any further questions or comments.

The North-East England Stem Cell Institute, a collaboration between the Universities of Durham and Newcastle, the Newcastle upon Tyne Hospitals NHS Foundation Trust and other regional partners.

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