Scottish Council on Human Bioethics

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Date: 15 June 2007 - UK House of Commons and House of Lords Joint Committee

Draft Human Tissue and Embryos Bill

The two Houses of Parliament have established a Joint Committee on the draft Human Tissue and Embryos Bill (Cm 7087) which was published by the Government on 17 May 2007.

Consultation response on behalf of the Scottish Council on Human Bioethics (SCHB):

Note: Not all questions will be addressed

The draft Bill overall

1. Are the proposals in the draft Bill necessary, sufficient and workable? Could the proposed outcomes be achieved by better means?

2. Does the regulatory architecture set out in the draft Bill contain the right balance between:
(i) Parliamentary control via primary legislation and secondary legislation (regulation making powers);
(ii) Regulation by the regulatory body (or bodies);
(iii) Appropriate flexibility and freedom for clinicians and researchers; and
(iv) Appropriate opportunities for individuals to access treatment.

The SCHB is of the opinion that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law.

Concerning the balance between legislation prepared by Parliament and regulations which may be established by regulatory authorities or ministers, the SCHB is of the view that the former should take priority, where possible. This is because the drafting of legislation enables all sections of society to take part in the discussions through the parliamentary process.

Where regulations and/or legislation are being considered they should, in so far as possible, anticipate future biological possibilities, even though it may be difficult to determine these developments.

In order to address the problem of possible new developments, legal provisions should state only what is specifically acceptable, thereby prohibiting all other procedures. This will then avoid an enumeration of prohibitions which may, with time, become obsolete, unclear and vague.
For example, new UK legislation with respect to reproductive cloning eventually enacted a provision indicating what was acceptable by stating that "*A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence*" (Section 1 of the Human Reproductive Cloning Act 2001). This was done in order to address misunderstandings resulting from only having prohibitions in existing legislation which did not specifically apply to human cloning.

The SCHB considers that the UK Parliament should ensure that it drafts all-encompassing legislation when preparing laws. This would minimise the issues that would have to be regulated *ad hoc* by other bodies which may be less representative of society.

In addition, the SCHB is of the view that it would be impractical for the UK Parliament itself to act as a regulatory body. Thus there is a need for a body such as the HFEA to be appointed which has the appropriate expertise to consider the issues that arise.
However, this body clearly needs to be accountable to Parliament and an appropriate parliamentary committee should be able to closely monitor any regulatory decisions.
The SCHB is also concerned that the present HFEA may have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

3. How should Parliament and the regulatory body or bodies ensure an appropriate ethical framework to secure and maintain public confidence?

In order to retain public confidence, the UK Parliament should sign and ratify the Council of Europe's ***Convention on Human Rights and Biomedicine (CETS No.: 164)***. This Convention has already been ratified by 20 European countries (with another 14 having signed their intention to ratify) and states in Article 18 that "*The creation of human embryos for research purposes is prohibited*."
If this is not undertaken, the SCHB believes that the UK would begin to be seen as ethically isolated by its neighbours and its reputation will be undermined.

PART 2 of the Draft Bill

Definitions

Clause 14 of the draft Bill revises the statutory definitions of 'embryo', 'egg', 'sperm' and 'gamete'. Clause 15 revises the statutory definition of 'nucleus'. Clause 14 also gives the Secretary of State regulation-making power to expand these definitions if it appears to him to be necessary or desirable to do so in the light of developments in science or medicine (subject to some restrictions).

7. (a) Do you agree with new definitions in the draft Bill of 'embryo', 'egg', 'sperm', 'gamete', 'nucleus'? If not, how would you propose to amend them?

The SCHB believes that a definition of an embryo should be given. An example could be: *"The early biological stages in time of a person*".
It also supports the definition of an embryo given in German legislation which indicates that any isolated totipotent cell which may divide and develop into an individual human being, once the necessary further conditions are provided[1], is also an embryo (see also answer to question 10).
It would then be up to scientists and society to give evidence that an entity cannot be regarded as an embryo.

The current meaning of embryo also includes human eggs "in the process of fertilisation". This has been criticised on the basis that a unique genetic identity is not formed until the process of fertilisation is complete. However, the SCHB cannot state, without any supporting evidence, that the starting point from which the protection of law should apply is the stage when two cells have formed - generally at around 36 hours.

The SCHB is aware of the desires of biomedical scientists to undertake research or therapy before fertilisation is complete, which currently may be prevented by provisions in the HFE Act that apply to research on embryos. However, the SCHB believes that to remove eggs in the process of fertilisation from the scope of regulation could open up dangerous loopholes and uncertainty.

Otherwise the SCHB agrees with the definition of 'egg', 'sperm', 'gamete' and 'nucleus'.

7. (b) Should the Secretary of State have the regulation-making power to expand these definitions as proposed in the draft Bill?

No, the Secretary of State should not have regulation-making power to expand these definitions as proposed in the draft Bill. These definitions should be defined by legislation following appropriate and democratic debates in parliament.

Inter-species embryos (for example, cytoplasmic hybrid embryos)

The text of the draft Bill (particularly in clause 17 and Schedule 2) reflects the position in the Government's White Paper that the creation of hybrid and chimera embryos in vitro is prohibited, but that a regulation-making power would allow Parliament to agree exceptions to that prohibition for research purposes.
On publication of the draft Bill, the Government announced that it now intends to accept (in part) the approach advocated by the Commons Science and Technology Select Committee, that legislation should provide for certain inter-species entities to be created for research purposes under licence by the Regulator within a 14-day limit. The Government proposes that the entities to be permitted should be limited to those listed in clause 17(2) inserted section 4A(5)(b) to (d) on page 9 of the draft Bill (see also paragraph 1.12 of the introduction to the draft Bill on page

[1] Section 8 of the German Embryo Protection Act of 13 December 1990.

ix). This would <u>exclude from the licensing regime</u> "pure hybrids" as described in clause 17(2) inserted section 4A(5)(a) and (e) on pages 9 and 10.
The Science and Technology Committee, in its recent Report "Government proposals for the regulation of hybrid and chimera embryos", goes further than the Government's new position and recommends that legislation should be permissive and provide that "in general, the creation of all types of human-animal chimera or hybrid embryos should be allowed for research purposes" under licence by the Regulator (recommendations 22 and 26 on page 63 of that Report). Furthermore, the Committee recommended that licensing should not allow for the development of interspecies embryos past the 14-day limit unless proved necessary.

8. Do you support:
(i) the approach signalled by the Government in the White Paper,
(ii) the new approach announced by the Government (as outlined above); or
(iii) the approach recommended by the Commons Science and Technology Committee?

The SCHB supports the approach signalled by the Government in the White Paper.
Further ethical discussion relating to the creation of human-nonhuman embryonic combinations can be found in the attached BioCentre Working Party report on the topic. Dr. Calum MacKellar (from the Scottish Council on Human Bioethics) was indeed the chair of this Working Party.

Research licences

In addition to the new provisions on inter-species embryos, clause 18 and Schedule 2 of the draft Bill consolidate the purposes for which licences for research can be granted and extend the principle purposes listed in paragraph 6 of Schedule 2.

8. How should Parliament approach legislating for those purposes for which licences for research may be granted in the future (arising out of future research) but that are not yet determined? Should such judgements be left to the regulatory body or bodies to determine?

The SCHB is of the opinion that the UK Parliament should sign and ratify the Council of Europe's ***Convention on Human Rights and Biomedicine (CETS No.: 164).*** This Convention has already been ratified by 20 European Countries (with another 14 having signed their intention to ratify) and states in Article 18 that *"The creation of human embryos for research purposes is prohibited*."
If this is not undertaken, the SCHB believes that the UK would begin to be seen as ethically isolated by its neighbours and its reputation will be undermined.

9. How should Parliament or the regulatory body or bodies take public views and public engagement into account?

The SCHB notes that in Switzerland many of the decisions relating to medical ethics are taken though referenda. This provides the means and the incentive for ordinary members of the general public to discuss and make a decision about the issues.

Embryo testing and sex selection practices

Clause 18 and Schedule 2 of the draft Bill propose changes to existing statutory limits on those activities that can be licensed. This covers conditions under which embryo testing may be carried out, for example to test for tissue compatibility that could be used to treat siblings with a life-threatening medical condition (tissue typing), or testing for an abnormality that may affect the embryo's capacity to result in live birth. It also covers the conditions under which practices involving sex selection may be licensed – where there is a particular risk of a woman giving birth to a child with a chromosomal abnormality involving a significant risk of developing a serious physical or mental disability, a serious illness or any other serious medical condition. Sex selection for non-medical reasons is not permitted, nor is it permitted to select specifically for an abnormality, such as deliberately choosing an embryo which would result in a deaf child.

10. What are your views on the provisions in paragraph 3 of Schedule 2 setting out the conditions under which (a) embryos can be tested and (b) sex selection practices can be carried out?

Because the definition of an embryo as well as its legal status are so dissimilar between countries, the SCHB would like to note that very different legislations in Europe have been developed concerning Preimplantation Genetic Diagnosis (PGD).
These different legislations also reflect the reality that only a limited amount of scientific information is currently available concerning the 'potency' of human totipotent cell(s) taken from the embryo in PGD. These are then used (and thereby destroyed in the process) to test the 'quality' of the original embryo.

But though no consensus regarding the exact ethical nature of totipotent cells has yet been reached internationally, the fact that these differences exist when considering PGD has frequently been overlooked in some countries.
For example, in the UK, there has often been a nearly unanimous acceptance by scientists and the general public that the moral status of totipotent cells used for PGD has finally been resolved after the 1990 Act. But this is unfortunate since it should be remembered that UK legislation was decided through the means of democratic votes and not after any unanimous scientific demonstration which everyone could accept. Indeed, an increasing number of persons in the UK remain uncertain as to whether the right decisions were made at all[2].

Thus, as long as our whole scientific and ethical decision making process continues to be based on democratic majorities rather than on rational and logical demonstrations, politicians, scientists, healthcare professionals and many amongst the general public will remain uneasy as to what is really being considered.
Because of this, legislation with respect to totipotent cells should never be seen as being built on unquestionable solid foundations to be used for future discussions concerning embryological research. Instead, it should simply be considered as the views of the majority at the time which could prove to be inappropriate when further results and understandings of the biological process are defined.

In some countries such as in the Republics of Ireland and Germany PGD has been made impossible or illegal.

In Germany this happened because in the ***Embryo Protection Act (12.13.1990)*** the embryo is protected from the one-cell stage of the fertilised egg until completed nidation in the uterus. Moreover the legal definition of an embryo is considered as:

- "*the fertilised egg from the moment of the fusion of the cell nuclei of egg and spermium, and*

- *every totipotent cell taken from an embryo since these cells have the potential to develop into a human individual*."[3]

This means that according to German legislation every cell of the 8-cell embryo (third-fourth day of embryonic development) is under the strongest possible protection of the German ***Embryo Protection Act*** since every cell is totipotent and legally qualifies as an embryo.
In addition, Paragraph 2 of the ***Embryo Protection Act*** leaves no possibility of discretion when it states that it is forbidden "*to dispose of an embryo, or to deliver, acquire, or use an embryo for purposes not serving its preservation*"[4]. Elisabeth Hildt summarises this when she explains that in German law "*a totipotent cell derived from a human embryo in its development is considered equivalent to a human embryo, as long as this cell is able to develop into a human being. Thus it is prohibited to destroy either an entire human embryo or a totipotent cell derived from a human embryo.*" [5]. This means that all biopsies of totipotent cells for research or analytical purposes such as PGD are forbidden even if the 'original' embryo is not harmed since the cells used for the analysis and their subsequent destuction can also be considered as embryos.

The SCHB notes that recent trends giving ever more choice in the field of reproductive technologies have also increased the number of embryos and foetuses being destroyed. For example, with PGD a number of embryos are created with only a few being selected and implanted (or frozen) resulting in a significant number of embryos being considered as 'waste'. Such a development took place in the case of the Hashmi couple, who fought for the right to have a tissue-matched IVF baby to save the life of their older son. In this case, six IVF cycles were undertaken and a large number of embryos created but without any success[6]. In the same way, the SCHB is very concerned that PGD may enable parents, in the future, to enter into a kind of 'embryonic creation and

[2] Anonymous, Cloning and stem cells, *Wellcome News*, Issue 21 Q4, 1999. p.5

[3] Wolfrum R, Zeller AC, Legal Aspects of Research with Human Pluripotent Stem Cells in Germany, *Biomedical Ethics*, 1999; Vol.4, No.3.

[4] Wolfrum R, Zeller AC, Legal Aspects of Research with Human Pluripotent Stem Cells in Germany, *Biomedical Ethics*, 1999; Vol.4, No.3.

[5] Hildt E.; Preimplantation diagnosis in Germany; *Biomedical Ethics*; 1996, Vol.1., No.2.

[6] Hashmis fail in 'saviour sibling' attempt, Bionews 9 July 2004, http://www.bionews.org.uk/new.lasso?storyid=2180

destruction relentlessness', whereby ever more embryos are created and destroyed with the aim of saving the life of one of their existing children.

Consent to storage and use of gametes and embryos

Clause 20 (and Schedule 3) make changes to existing provisions about consent to, and use of, gametes and embryos.

11. What are your views on the proposed changes to consent provisions?

The SCHB notes that patients should be asked to think about what they want to do with their potential leftover embryos before they are created. This is in agreement with Dr Richard Kennedy, secretary of the British Fertility Society and consultant gynaecologist at the Centre for Reproductive Medicine in Coventry, who indicated that "*it would be helpful to raise the issue of 'what will you do with these embryos?' before they are created*."[7]

The SCHB is of the view that an embryo belongs to both parties whose gametes were used to create an embryo. Both parties are therefore responsible for the embryo. Where possible, the continued existence of a frozen embryo should be preferred over destruction.

Concerning the creation of human embryos *in vitro*, the SCHB notes that in countries such as Germany, Austria, Italy and Ireland it is considered unethical to create human embryos *in vitro* if they are not immediately implanted into the mother. I.e. only the exact number of embryos are created, in the first place, for IVF. This happens in order to avoid the difficult problem, which exists in the UK, of having an ever increasing stock of frozen, unwanted and supernumerary embryos generally destined for destruction.

The SCHB recognises that even though an unacceptable large number of stored embryos does unfortunately exist in the UK, it would be preferable for these embryos to be given for adoption instead of being destroyed. Though some of the problems relating to the important biological 'bonds' that should exist between parents and children do not exist in this case, the adoption of embryos, in a similar way as the adoption of children, is a very positive solution to an already existing difficult situation. This is in contrast to *creating* difficulties in kinship identities and the related biological 'bonds' which is what is happening in donor insemination.
The SCHB would thus like to encourage the adoption by infertile couples of supernumerary embryos[8].

Treatment conditions

Clause 21 of the draft Bill proposes changes to the conditions of licences for providing treatment services. It proposes to remove from the existing conditions of licences the requirement to take account of "the need of that child for a father" before treatment services can be provided.

12. What are your views on the proposal in the draft Bill to remove from the existing conditions of treatment the requirement to take account of "the need of that child for a father" before treatment services can be provided? Clause 21 also extends the requirement to take account of the welfare of the child to all treatment services (not just those currently covered by the 1990 Act) as a result of the European Tissue Directive.

The SCHB is of the view that the requirement to take account of "the need of the child for a father", as part of considering the welfare of the child, should be replaced with "the need of the child for a father and a mother" in the new legislation.

The SCHB notes that in the recent HFEA consultation document, it is indicated that[9]:

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[7] Sarah-Kate Templeton, Spare embryos 'should be donated to infertile couples', The Sunday Herald, *21 September 2003: http://www.sundayherald.com/36912*

[8] This should take account of the risk of incest if many embryos are adopted in a common location.

[9] Tomorrow's children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born of assisted conception treatment, Human Fertilisation and Embryology Authority, 2005, paragraph 2.3., http://www.hfea.gov.uk/AboutHFEA/Consultations/Welfare%20of%20the%20child%20Tomorrows%20Children.pdf

"Studies conducted over the past decade suggest that, despite initial concerns, children born to lesbian couples compare well with other assisted conception children in terms of emotional, behavioural and gender development."

However, the SCHB notes that such a statement could lead to misconceptions. Indeed, it is not because children born to lesbian couples compare well, psychologically, with other assisted conception children that there will not be any possible complications in the future. The studies undertaken, so far, are incomplete and have often only examined pre-adolescent children. These may not be as concerned about their identity or their family circumstances as when they grow older. It is possible that these children may only become aware of any psychological problems when they become adults or consider having children of their own later on in life.

13. What are your views on the approach to the welfare of the child provisions in clause 21?

Storage limits

Clause 22 of the draft Bill proposes to increase the statutory storage period for embryos from 5 years to 10 years to match the statutory storage period for gametes.

14. Do you support the proposal to increase the storage period from 5 to 10 years? Should the storage period for gametes and embryos be limited by statute at all?

The SCHB is of the opinion that, as in Germany and Italy, supernumerary embryos should not be created and that couples should be appropriately counselled concerning the use and destiny of their embryos before they are created.

Register of information and access to the Register

Clause 32 of the draft Bill replaces existing legislative provisions about the Register of information with new provisions about the Register of information that RATE must keep and the entitlements of certain persons to access information on the Register. This includes extending to a donor-conceived person about to enter a civil partnership the existing provision allowing a donor-conceived person to obtain information about whether they are related to the person they intend to marry. Clause 33 contains restrictions on the disclosure of information.

15. What are your views on the provisions about the Register and access to it in clauses 31, 32 and 33 of the draft Bill?

Whilst opposing donor assisted conception, the SCHB agrees that:

- people should be able to obtain information about whether or not they were donor-conceived and about their donor (including identifying information where lawful) from the age of 16 rather than, as now, from the age of 18.

- donor-conceived people should be able to access information to discover whether they are related to someone with whom they intend to have children.

- non-identifying information about offspring could be released.

- donor-conceived people should be able to access information about their donor-conceived siblings (where applicable).

- natural children of donors should be able to access information about their donor-conceived siblings and vice-versa. This information should include identifiable details.

PART 3 of the draft Bill

Parenthood and the use of sperm or transfer of embryo after death

Part 3 of the draft Bill (clauses 39 to 64) makes provision for legal parenthood in cases involving assisted reproduction, including making more precise provision for unmarried couples or partners and clarifying provisions about consent that must be provided before treatment.

16. What are your views on the provisions covering parenthood and consent in Part 3 of the draft Bill? Are there any particular provisions in these clauses you would seek to change?

In the absence of legal ties, the SCHB is of the view that a lack of evidence regarding the commitment of a partner to another may constitute a similar lack of evidence regarding his or her commitment to parenthood.

The SCHB is also of the view that the sperm of a deceased man should not be used to create a child.

PART 4 of the draft Bill and other provisions

Legislating for future scientific development

In certain places, the draft Bill seeks to legislate now to regulate future scientific developments that are necessarily uncertain. In particular, it seeks to make provision:
(i) for Parliament to pass Regulations making the sale, supply and advertisement of sperm sorting kits an offence, if such kits are developed in the future (clause 65); and
(ii) for Parliament to pass Regulations to allow relevant provisions of the Act to have effect in cases where an egg or an embryo has been created from mitochondrial material provided by 2 women (sometimes called "artificial gametes") (clause 34).

17. Is it either desirable or appropriate for Parliament to seek to legislate in this way for future technology, both in general terms and in the particular cases identified? Is such legislation likely to be legally effective?

The SCHB believes that it is desirable and appropriate for Parliament to seek to legislate for future technology, both in general terms and in the particular cases identified. Indeed, it is always preferable to consider the ethical issues relating to a possible procedure before it has reached the stage when it can be used.

The SCHB is of the view that the selling, supplying or advertising of kits (or their component parts) which may be used for the purpose of selecting the sex of a child should be prohibited.

In agreement with a number of other countries in Europe, the SCHB is of the opinion that surrogacy should be prohibited because of the grave psychological and social risks that may be created by such a procedure. These include psychological and social risks for (1) the comissioning parents, (2) the surrogate mother, her eventual partner and existing children in addition to (3) the child created.

Embryo transfer in treatment

The draft Bill does not cover regulations relating to the conditions of transfer of embryos during treatment.

18. Should this be a matter for the regulatory body? Or for the National Institute for Health and Clinical Excellence (NICE)? Should it be regulated at all?

Other issues

19. Are there any other provisions in the draft Bill, or provisions you would like to see in the draft Bill, on which you would like to give your views?

- The SCHB is uncertain as to the manner in which the difference between a 'human' inter-species embryo and an 'animal' inter-species embryo in the draft Bill is defined and the manner in which such a decision would be made. Indeed, Section 17 (5) (d) defines an inter-species embryo as a 'human' embryo that has been altered by the introduction of one or more animal cells. But what about animal embryos that have been altered by the introduction of one or more human cells? How are these latter embryos addressed?

- The SCHB would like to see new provisions in the draft Bill prohibiting the implantation of (a) human sperm and (b) animal 'inter-species embryos' into animals.

Moreover, there is apparently no complete prohibition in UK law with respect to placing human sperm and eggs together in the uterus of another animal[10]. However, in 1984, an experiment was reported in Australia in which researchers introduced human eggs and sperm into the fallopian tube of a sheep[11].

- The SCHB believes that the current practice, in the UK, of obtaining subsidised IVF treatment in exchange for donating eggs may constitute a breach of the ***European Convention on Human Rights***. This is especially the case since the specified limit for donor expenses is £250 as defined by the **Human Fertilisation and Embryology Authority**. However, where the price of IVF is reduced in exchange for egg donation, the donor often benefits to the tune of nearly £2000. And the **Council of Europe** has indicated that the human body and its parts should not, as such, give rise to financial gain or any other advantage whatsoever comparable to a financial gain such as benefits in kind[12].

- The SCHB does not agree that in establishing an ethical basis for the regulation and legislation of Human Reproductive Technologies, the Warnock Committee's gradualist approach to the status of the embryo is ethically sound.
The SCHB is of the opinion that the precautionary principal should be applied concerning the status of the human embryo. In other words, until explicit scientific proof of the contrary can be provided, a human embryo, as soon as it is created, should be considered as having the same moral status as an adult human person.
The Council also notes that it would be inappropriate not to address the debate relating to the moral status of the human embryo in any new enquiry. This is because the debate is crucial to the manner in which many consider the different biomedical procedures. In other words, it is not sufficient to dogmatically maintain that a conclusive and final decision has already been taken concerning this issue. It is because human personhood and dignity are not decided through majority votes that a considerable debate remains concerning the status of the early embryo!
The Council notes, in this regard, that the process of human development is a continuous one in which any demarcation would be arbitrary and merely conventional as exemplified by the different upper time limits for abortions and embryological destructive research across Europe. Within the development process it is indeed impossible to indicate a non-arbitrary point of transition from human non-person to human person.

And although figures are not available, it is highly probable that millions of people in the UK believe that human embryos cannot just be considered as piles of cells. Instead, they believe that they can be invested with full human dignity or given the benefit of the doubt thereof. For these people, the creation and destruction of human embryos would be considered as extremely offensive. Something similar to the creation of human infants for destructive biomedical research.
Thus, from an ethical perspective, the deep offence arising in these millions of people in the UK by the creation and destruction of these entities could not be compensated by the possible advantages perceived by those who believe that such research may, or may not, give rise to treatments for biological disorders. This is especially the case in the light of new research (June 2007) which indicates that good alternatives may exist to the creation and destruction of embryos in order to obtain human embryonic stem cells[13].

Moreover, it is because the creation of human embryos for destructive research is considered to be deeply offensive and unethical in almost all continental European states that scientists undertaking such research would, most probably, end-up in prison in countries such as France, Germany and Italy.

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[10] Robert G.Lee, Derek Morgan, Human Fertilisation & Embryology: Regulating the Reproductive Revolution, Blackstone Press Ltd., 2001, p. 87.

[11] Experiment reported by Carl Wood and Anne Westmore in their book entitled 'Test-Tube Conception', George Allen & Unwin, Sydney, 1984. In Robert G.Lee, Derek Morgan, Human Fertilisation & Embryology: Regulating the Reproductive Revolution, Blackstone Press Ltd., 2001, p. 87.

[12] Though the ***Additional Protocol to the Convention on Human Rights and Biomedicine, on Tranplantation of Organs and Tissues of Human Origin*** does not address reproductive cells, it is an indication of the intention of the Council of Europe. http://conventions.coe.int/treaty/en/treaties/html/186.htm

[13] Rick Weiss, **Scientists Use Skin To Create Stem Cells,** Washington Post, 7 June 2007; http://www.washingtonpost.com/wp-dyn/content/article/2007/06/06/AR2007060601345_pf.html