

## Scottish Council on Human Bioethics

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### Consultation response to the UK House of Commons - Science and Technology Committee

## Human Reproductive Technologies and the Law

### Executive Summary

The Scottish Council on Human Bioethics considers that the HFEA should become more accountable to Parliament. An appropriate parliamentary committee, such as the Science and Technology Committee of the House of Commons, should be able to closely monitor any regulatory decisions of the HFEA and intervene if it feels that a particular issue requires wider discussion and consideration.

The SCHB is also concerned that the 18 members of the HFEA are often selectively appointed to only represent certain views and that they have too much power to act, without consultation with Parliament, in the important area of human reproductive technologies.

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*The Science and Technology Committee announced the following terms of reference for its inquiry into Human Reproductive Technologies and the Law. These were drawn up after analysing a report of the online consultation produced by the Hansard Society:*

*1. To consider a) the balance between legislation, regulation and reproductive freedom; b) the role of Parliament in the area of human reproductive technologies; and c) the foundation, adequacy and appropriateness of the ethical framework for legislation on reproductive technologies.*

### Scottish Council on Human Bioethics Response:

#### a) the balance between legislation, regulation and reproductive freedom

1.1. The SCHB agrees that reproductive decisions should not be left exclusively to the persons concerned since this would leave reproductive technologies open to exploitation. For example, some persons in certain circumstances may act for their own immediate interests rather than examine the wider ethical issues such as those pertaining to the child being considered and society as a whole. No person or couple exists in isolation. In other words, there is clearly a need for regulation and/or legislation.

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

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

1.4. 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.

1.5. The SCHB is also of the opinion that a committee, such as the past Warnock committee, would be best suited in assessing the relevant ethical framework and the drafting of preliminary recommendations. But its composition must reflect the diversity of views within society.

#### b) the role of Parliament in the area of human reproductive technologies

1.6. The SCHB considers that the UK Parliament should ensure that it drafts all-encompassing legislation when preparing laws in the area of human reproduction. This would minimise the issues that would have to be regulated ad hoc by other

bodies which may be less representative of society.

1.7. 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.

1.8. The SCHB notes that the question relating to whether or not the area of human reproductive technologies becomes a devolved matter for the Scottish Parliament and the Northern Ireland Legislative Assembly should be considered.

c) the foundation, adequacy and appropriateness of the ethical framework for legislation on reproductive technologies

1.9. The SCHB is concerned that the current ethical framework underlying UK legislation is often little more than situation and utilitarian ethics. Instead, an acknowledgement of human identity and personhood with, as a consequence, the protection of human dignity should be the underlying basis on which to draft new legislation.

1.10. In this respect, the SCHB recognises a need to determine whether or not animal-human hybrid embryos could be acknowledged as having a human identity and personhood and whether or not they should be addressed under 'human' legislation. The Council notes that public debate is urgently required in this regard.

1.11. Moreover, the SCHB emphasises that legislation on reproductive technologies should be evidence-based. For example, it is currently often assumed that the early embryo does not have the same status as an adult human person without any scientific evidence being presented. The Council notes that it would be inappropriate not to address the debate relating to the moral status of the 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!

*2. To consider the provisions of the Human Fertilisation and Embryology Act 1990 in the context of other national and international legislation and regulation of medical practice and research.*

*To include related legislation such as the EU human tissue directive, and law covering human rights, surrogacy, adoption and abortion.*

*To include relevant declarations and statements by international bodies.*

*To compare the safety and welfare provisions of the Human Fertilisation and Embryology Act 1990 with those that cover other areas of medical practice.*

**Scottish Council on Human Bioethics Response:**

2.1. The SCHB notes that UK legislation concerning embryo research is generally a lot more liberal than elsewhere in the world and that it would be highly desirable for UK legislation to encompass relevant international declarations and conventions.

In this regard, the SCHB is of the opinion that possible new legislation in the UK relating to Human Fertilisation and Embryology should be amended so that it becomes compliant with the following provisions of international declarations, legislation and regulation:

United Nations Educational, Scientific and Cultural Organization:

- The draft Universal Declaration on Bioethics (currently being prepared by UNESCO)
- The Universal Declaration on the Human Genome and Human Rights<sup>1</sup>
- The International Declaration on Human Genetic Data<sup>2</sup>

Council of Europe

- Convention on Human Rights and Biomedicine (European Treaty Series - No. 164)<sup>3</sup>: Article 18 (2) (Research on embryos in vitro) which states that:

"The creation of human embryos for research purposes is prohibited."

- Additional Protocol on the Prohibition of Cloning Human Beings (European Treaty Series - No. 168)<sup>4</sup>: Article 1 which states that:
  - (1) "Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."
  - (2) "For the purpose of this article, the term human being "genetically identical" to another human being means a human being sharing with another the same nuclear gene set."

#### European Union

- Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

2.2. Finally, the SCHB concurs 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.

2.3. For the same precautionary reasons, the SCHB supports the definition of an embryo given in German legislation which indicates that any totipotent cell, extracted from an embryo which may divide and develop into an individual human being once the necessary further conditions are provided<sup>5</sup>, is also an embryo.

2.4. 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.

*3. To consider the challenges to the Human Fertilisation and Embryology Act 1990 from a) the development of new technologies for research and treatment, and their ethical and societal implications and b) recent changes in ethical and societal attitudes.*

*To include new areas of research, treatments and interventions, such as cloning, cell nuclear transfer, transplants of ovarian and testicular tissue, embryo splitting, selection of genetic characteristics (including sex selection), stem cell therapy and the use of immature gametes.*

#### **Scottish Council on Human Bioethics Response:**

3.1. The SCHB considers that the Human Fertilisation and Embryology Act 1990 is no longer capable of addressing new developments in embryology. This is reflected by the possibility for research to be permitted by omission and the ever-increasing number of court cases being initiated to provide additional clarifications to the Act.

3.2. New developments, which presently exist in a legal vacuum, should be regulated in any new legislation: See Annex A (HFEA and new human sperm, eggs and embryos) and B (HFEA and new human-animal hybrid entities).

3.3. Moreover, in a similar manner to Article 4 of the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography, the SCHB agrees that UK legislators should consider the possibility of drafting bioethical extra-territorial provisions making it an offence for UK nationals and habitual residents going abroad to undertake procedures which are prohibited in the UK.

*4. To consider the composition, expertise and approach of the Human Fertilisation and Embryology Authority, its code of practice, licensing arrangements and the provision of information to patients, the profession and the public.*

#### **Scottish Council on Human Bioethics Response:**

4.1. The SCHB is of the opinion that the current HFEA does not adequately regulate new developments and seems to excessively support scientific research, without adequate weight being given to other views and considerations.

In this respect, the SCHB notes that the absence of any minority reports often indicates a unanimous decision. This suggests that the composition of the HFEA does not adequately reflect the wide spectrum of views within society. Indeed, many believe that the 18 members of the HFEA are selectively appointed to only represent certain views.

4.2. Therefore, the SCHB proposes that the HFEA, or future equivalent body, should include individuals representing very

different viewpoints, thereby better reflecting society. If this is not done, a false and misleading impression of unanimity will be presented with the HFEA only making decisions 'for' society without being representative of society.

4.3. New solutions should be considered to enable the general public to become better informed and more engaged in decision-making relating to what should be acceptable. In other words, a body, such as the HFEA, should undertake sufficient and appropriate consultations of the general public.

Moreover, the Houses of Lords and Commons, as the bodies representing the UK members of society, should be more involved in the decisions of the HFEA.

4.4. Concerning the dual role of the HFEA relating to its licensing and regulatory powers, the SCHB is of the opinion that the licensing of interventions and procedures should remain the responsibility of the HFEA but that the regulation of any new biological or reproductive possibilities should take place in collaboration between the experts of the HFEA and the democratic representatives of Parliament.

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<sup>1</sup> [http://portal.unesco.org/en/ev.php@URL\\_ID=13177&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php@URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html)

<sup>2</sup> [http://portal.unesco.org/shs/en/file\\_download.php/6016a4bea4c293a23e913de638045ea9Declaration\\_en.pdf](http://portal.unesco.org/shs/en/file_download.php/6016a4bea4c293a23e913de638045ea9Declaration_en.pdf)

<sup>3</sup> Signed by 31 of the 45 Council of Europe Members States, <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc>

<sup>4</sup> Signed by 29 of the 45 Council of Europe Members States, <http://conventions.coe.int/Treaty/en/Treaties/Word/168.doc>

<sup>5</sup> Section 8 of the German Embryo Protection Act of 13 December 1990