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Human Fertilisation and Embryology Bill **[HL]**

Bill 70 of 2007-08

The Bill would revise and update legislation for assisted reproduction and also change the regulation and licensing of the use of embryos in research and therapy. It includes provisions for research on different types of embryos, and proposes changes to definitions of legal parenthood for cases involving assisted reproduction.

The Bill extends to the whole of the UK,

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Summary

The *Human Fertilisation and Embryology Bill* would revise and update legislation for assisted reproduction and also change the regulation and licensing of the use of embryos in research and therapy. It includes provision for research on different types of embryos, and proposes changes to definitions of legal parenthood for cases involving assisted reproduction.

The *Human Fertilisation and Embryology Act 1990* (as amended) provides the current legislative framework. It was largely based on a Committee of Inquiry, appointed in 1982, chaired by Baroness Warnock. The Committee's Report (the Warnock Report) was published in 1984.

A draft Bill, the *Human Tissue and Embryos Bill*, was scrutinised by a Joint Committee of both Houses. Some changes proposed to the *Human Tissue Act*, such as the establishment of a new body called Regulatory Authority for Tissue and Embryos (RATE), have been dropped. The change in the name of the Bill reflects that change.

The main elements of the Bill are:

- ensuring that the creation and use of all human embryos outside the body – whatever the process used in their creation – are subject to regulation;
- a ban on selecting the sex of offspring for non-medical reasons;
- retention of a duty to take account of “the welfare of the child” when providing fertility treatment, but removal of the reference to “the need for a father”;
- provisions to recognise same-sex couples as legal parents of children conceived through the use of donated sperm, eggs or embryos;
- altering restrictions on the use of HFEA-collected data to make it easier to do follow-up research;
- provisions clarifying the scope of legitimate embryo research activities, including regulation of “inter-species embryos” (embryos combining human and animal material).

The Bill had its Second Reading in the House of Lords on 21 November 2007. Its Committee Stage was between 3 and 12 December 2007. The Report Stage was between 15 and 28 January 2008 and the Bill had its Third Reading in the House of Lords on 4 February 2008. Its First Reading in the House of Commons was on 5 February 2008. It is due to have its Second Reading on 12 May 2008.

Amendments to abortion law may be introduced during the passage of the Bill.

Subject to certain provisions, set out in clause 67, the Bill extends to England and Wales, Scotland and Northern Ireland.

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I A brief history of human fertilisation and embryology regulation in the UK

a. *The Warnock Report*

The birth of the world's first baby conceived using *in vitro* fertilisation (IVF), in July 1978, and advances in fertilisation and embryology led to the appointment of a Committee of Inquiry in 1982. Chaired by Baroness Warnock, it was established "against [a] background of public excitement and concern" about human fertilisation and embryology.¹ It had the following terms of reference:

To consider recent and potential developments in medicine and science related to human fertilisation and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.²

The Committee reported in 1984 (the Warnock Report).³ It recommended the establishment of a new statutory licensing authority to regulate both research and infertility services. The authority would be given two functions: to grant licences to those wishing to offer infertility treatment; and to grant licences to researchers wishing to work with human gametes (sperm and eggs) and embryos.⁴

The Warnock Report also set out a number of principles that for the first time provided an ethical framework for embryo research. Those principles included: according a special moral status to the human embryo; permitting human embryo research only under licence from a regulator; and placing a 14-day limit on that research.⁵

In March 1985 the Medical Research Council (MRC) and Royal College of Obstetricians and Gynaecologists (RCOG) founded the Voluntary Licensing Authority for Human *in vitro* Fertilisation and Embryology (VLA)

b. *The Human Fertilisation and Embryology Act 1990 and the establishment of the Human Fertilisation and Embryology Authority (HFEA)*

In 1987, following a period of consultation, the Government published a White Paper, *Human Fertilisation and Embryology: A Framework for Legislation*, in which it committed itself to legislation.⁶ The legislation which subsequently came into being was the *Human Fertilisation and Embryology Act 1990* (the HFE Act). This received Royal Assent on 1

¹ *Report of the Committee of Inquiry into Human Fertilisation and Embryology* [The Warnock Report], 1984, Cm 9314 para 1.2

² *Ibid* para 1.2

³ *Ibid*

⁴ *Ibid* para 13.6

⁵ *Ibid* chapter 11

⁶ The Government issued a consultation document in 1986, the responses to which formed the basis for the White Paper entitled *Human Fertilisation and Embryology : A Framework for Legislation*, November 1987 Cm 259

November 1990. In the Commons debate on the Bill, the then Secretary of State for Health, Kenneth Clarke, commented on the prior consultation process:

[It] brought in a number of responses - indeed, a scale of responses that was quite out of the ordinary for the kind of public consultation exercises that accompany many measures before they are brought before the House. We received views not just from organisations and lobbies and the leading medical scientific, legal and religious bodies, but also from many individual members of the public who feel deeply, on one side or the other, about the issues.⁷

In the same debate, while the specifics of embryo research generated much discussion and debate, the need for there to be regulation appears to have been consensual:

Mr Clarke: I do not wish to anticipate debate, but I believe that the vast majority of right hon. and hon. Members would like there to be some statutory control.

The new statutory body, an independent body to be called the Human Fertilisation and Embryology Authority, covers four main treatments to be licensed-artificial insemination by donor, in vitro fertilisation and egg and embryo donation. If the House agrees with the decision reached in another place, the authority will also license research involving human embryos⁸

On Royal Assent the HFE Act implemented many of the Warnock Report recommendations and provided a legislative framework for the establishment of the Human Fertilisation and Embryology Authority (HFEA), an executive, non-departmental public body, the first statutory body of its type in the world.⁹

c. *Changes to the Legislation*

The HFE Act has subsequently been modified by the *Human Fertilisation and Embryology (Disclosure of Information) Act 1992*, and the *Human Fertilisation and Embryology (Research Purposes) Regulations SI 2001/188*, which have changed how the HFEA carries out aspects of its regulation. One of the more controversial aspects of this was the provision to allow for “therapeutic cloning” in the 2001 Regulations.¹⁰ This means that scientists can apply for a licence to clone human embryos provided they intend to use them to study disease in a laboratory situation only. A licence allows scientists to create human embryos by inserting the nuclei from human cells into human eggs, a process known as somatic cell nuclear transfer (SCNT). In the UK, research on human embryos is only permitted for certain purposes.

This broadened the scope of the type of licence that the HFEA could award, but the actual remit of the HFEA has remained unchanged. The Library Research Paper, [Stem Cell Research and Regulations under the Human Fertilisation and Embryology Act 1990 \(Revised edition\)](#), provides further information on changes in legislation at this time.

⁷ HC Deb 2 April 1990 c915

⁸ HC Deb 2 April 1990 c.918

⁹ [HFEA website](#) [on 2 May 2008]

¹⁰ [“UK gives go-ahead for human cloning”](#), *New Scientist*, 27 February 2002,

The EU Tissues and Cells Directive was adopted by the Council of Ministers on 2 March 2004 and published in the Official Journal of the European Union on 7 April 2004. It introduced new EU-wide legal requirements for anyone involved in the donation, procurement, preservation, testing, processing, storage and distribution of human tissue and cells (but not embryos). The HFEA and the Human Tissue Authority (HTA) are the two named Competent Authorities in the UK under the Directive for regulating establishments which store tissue for human application and for governing the quality and safety of tissue and cells used for human application. Secondary legislation implementing the Directive was passed in April 2007.

II Development of the current Bill

Prior to the publication of the draft Bill (*Human Tissue and Embryos (Draft) Bill*) there was a series of White Papers, consultations and Committee Reports, concerning various issues addressed in the draft Bill. Chapter Two of a Report on the draft Bill by a Joint Committee of both Houses gives a history of developments in this area (further Parliamentary and other resources are listed in Appendix 1).¹¹

6. It is nearly thirty years since the birth of the first child conceived using *in vitro* fertilisation (IVF). In light of scientific developments in the fertilisation and embryology field, a Committee of Inquiry was appointed in 1982, chaired by Baroness Warnock. The Committee's Report (the Warnock Report) published in 1984 concluded that there was an urgent need for a scheme of active monitoring and regulation in this area.¹²

Following a process of public consultation through Green and White Papers, Parliament passed the Human Fertilisation and Embryology Act 1990 (the 1990 Act) which implemented many of the recommendations of the Warnock Report and in particular provided a legislative framework for:

- The creation of human embryos outside the body and their use in treatment
- Use of human embryos in research
- Use of donated gametes and embryos
- The establishment of the Human Fertilisation and Embryology Authority (HFEA) with responsibility for licensing, monitoring, information and advice on human embryo research and assisted reproduction treatment.

7. The 1990 Act has since undergone a series of modifications. In 1992, some of the information disclosure restrictions in the original Act were revised after they were found to be overly restrictive.¹³ In 2001, the purposes for which embryo research could be licensed were extended to include "increasing knowledge about the development of embryos", "increasing knowledge about serious disease", and "enabling any such knowledge to be applied in developing treatments for serious disease", thus paving the way for embryonic stem cell research.¹⁴ Meanwhile, in 2001 the Human Reproductive Cloning Act was passed

¹¹ Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill Report 1* August 2007 HL 169-I/HC630-1 2006-07

¹² Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, Cm 9314

¹³ *Human Fertilisation and Embryology (Disclosure of Information) Act 1992*

¹⁴ *The Human Fertilisation and Embryology (Research Purposes) Regulations 2001*

outlawing any attempt to create a child through a process other than fertilisation using sperm and egg. In 2004, Parliament agreed that donor-conceived children would be able to access the identity of their sperm, egg or embryo donor on reaching the age of 18.¹⁵

8. There have also been developments in the law on human tissue. Following a 2002 Department of Health review of the law on human organs and tissues, the Human Tissue Act 2004 established the Human Tissue Authority (HTA). Also in 2004, the European Union Tissue Directive set EU-wide standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.¹⁶ The Scottish Parliament passed the Human Tissue (Scotland) Act in 2006.

9. Separate from this legislative process, the Department of Health undertook a review of its 'arm's length bodies' in an effort to improve efficiency and cut bureaucracy.¹⁷ One of the conclusions of this review was a proposal to replace, by April 2008, the HFEA and the HTA with a single body with responsibilities across the range of human tissue and cells, to be known as the Regulatory Authority for Tissue and Embryos (RATE). Proposals for RATE form Part 1 of the Draft Bill.

10. In 2005 the House of Commons Science and Technology Select Committee published a report on *Human Reproductive Technologies and the Law*.¹⁸ The preceding inquiry investigated the legislative framework provided by the 1990 Act and challenges presented by technological advance and "recent changes in ethical and societal attitudes." In light of the Committee's Report, and legislative changes that had already been made, the Department of Health undertook a review of the 1990 Act.

11. The Government's rationale for this review was that:
"The [1990] Act has stood the test of time well, and is a tribute to the foresight of its creators ... The Act and the regulatory system it established have instilled public confidence in the safe and ethical use of assisted reproduction technology subject to appropriate safeguards.
However, it was never expected that the Act would remain forever unchanged in this area of fast-moving science."¹⁹

12. The Government conducted a public consultation exercise in 2005 and received 535 formal responses from around 100 stakeholder groups and organisations and a wide range of individual professionals, patients and members of the public. An independently commissioned summary of responses was

¹⁵ *Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004*

¹⁶ Directive 2004/23/EC of the European Parliament and the Council of the European Union. Secondary legislation implementing the Directive was passed in April 2007

¹⁷ *Report on Reconfiguring the Department of Health's Arm's Length Bodies*, Department of Health, July 2004

¹⁸ House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law*, 2004–05, HC 7–1

¹⁹ *Review of the Human Fertilisation and Embryology Act: A Public Consultation*, Department of Health, 2005

published in March 2006.²⁰ In December 2006, the Department of Health responded with its proposals for revised legislation in a White Paper.²¹ In 2006, the House of Commons Science and Technology Select Committee began an inquiry into the proposals in the White Paper for the regulation of hybrid and chimera embryos reporting in March 2007.

In the White Paper, *Review of the Human Fertilisation and Embryology Act* (December 2006) the Government presented its initial proposals to revise the legislation. The review was undertaken to ensure that “the law and regulation remained effective and fit for purpose given the pace of scientific developments and public attitudes associated with them” and specifically aimed to address:

- the development of new procedures and technologies in assisted reproduction,
- international developments in the standards that clinics have to meet,
- possible changes in public perceptions and attitudes on complex ethical issues,
- the need to ensure the continued effectiveness of regulation, to reduce uncertainty and the scope for legal challenges.

1. Joint Committee

The resulting *Human Tissue and Embryos (Draft) Bill*, published on 17 May 2007, was subject to pre-legislative scrutiny by a Joint Committee of both Houses which reported in August. The Joint Committee’s main recommendations related to three areas:

- the regulatory regime proposed by the Government,
- issues around the approval of inter-species embryo research,
- ethical issues surrounding fertility.

The Joint Committee took oral evidence from 46 witnesses including scientific experts, representatives of interested organisations and individuals. It held an evening discussion forum with 11 organisations representing particular moral and ethical perspectives. It received 115 submissions of written evidence and more than 100 other submissions. The Committee also conducted an online consultation via its website.²²

The Joint Committee Report abstract gives an overview of its recommendations²³

The Human Tissue and Embryos (Draft) Bill, published on 17 May, sets out the Government’s proposals to update the law on assisted human reproduction. A Joint Committee of both Houses of Parliament was set up to undertake pre-legislative scrutiny on the Draft Bill and ordered to report by 25 July. Assisted reproductive technology, treatment and research have developed significantly since the Human Fertilisation and Embryology Act was passed in 1990. These developments have raised ethical, scientific, legal and social issues worthy of

²⁰ Report on the Consultation on the Review of the *Human Fertilisation and Embryology Act 1990*, prepared for Department of Health. People Science and Policy Ltd, March 2006

²¹ Department of Health, *Review of the Human Fertilisation and Embryology Act*, , December 2006

²² [Joint Committee on the Human Tissue and Embryos \(Draft\) Bill](#) website [on 2 May 2008]

²³ Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill Report*, 1 August 2007 HL 169-I/HC630-1 2006-07

detailed consideration. We welcome the Draft Bill and the opportunity to undertake pre- legislative scrutiny in this important area. However, there are a number of significant areas where we challenge the Government's approach.

First, we reject the Government's proposals to merge the existing regulators to form RATE—the Regulatory Authority for Tissue and Embryos. The evidence we received on the merger proposal was overwhelmingly against setting up RATE. Retaining the HFEA and the HTA will provide better regulatory oversight and we recommend amending the Draft Bill to provide a clear framework of devolved regulation giving greater regulatory freedom and authority to the regulator and clinicians except where there is a good reason to do otherwise.

Second, we ask the Government to revisit its approach to inter-species embryos. If Parliament supports the creation and use of inter-species embryos for research—and we believe the issue should be put to a free vote in both Houses—we recommend that legislation should provide a general definition that the regulator can interpret and apply to individual research applications within the principles set out by Parliament. This contrasts with the Government's approach to try to define now in legislation new types of interspecies embryos that may emerge in the future.

Third, the Draft Bill proposes to remove the requirement to take into account the need of the child for a father from the current conditions of every licence to provide IVF treatment services. Again, we recommend a free vote on the issue. The balance of view of the Committee is that the provision should be retained but in a form that makes clear (in keeping with other provisions in the Draft Bill) that it relates to the need for a second parent.

Finally, in relation to both inter-species embryos and the 'need for a father' provisions, we have recommended a free vote in Parliament because of the profound nature of the ethical issues involved. If Parliament is being asked to make judgements on such issues, it should have an established mechanism to allow it to do so with input and engagement from those holding views across the ethical spectrum. We therefore call for Parliament to establish a joint committee on bioethics.

On 8 October 2007 the Government published its response to the Joint Committee's report on the *Human Tissue and Embryos (Draft) Bill*.²⁴ It stated that the proposal to establish RATE would be dropped from the *Human Tissue and Embryo Bill* and that this matter would be reconsidered in the future:

14. The proposal to establish the Regulatory Authority for Tissue and Embryos (RATE) arose from DH's review of its arm's length bodies in 2004. This was part of the wider Government aim of minimising and modernising the bureaucracy that goes with the provision of public services. The review recommended the replacement of the HFEA and the Human Tissue Authority (HTA) with one single authority.

²⁴ [Government Response to the Report from the Joint Committee on the Human Tissue and Embryos \(Draft\) Bill](#), CM 7209 8 October 2007 p6-7

15. The proposal would provide for one competent authority to be responsible for the regulation and inspection of all functions relating to the whole range of human tissue. RATE would ensure that in these closely linked areas, common principles and standards would be applied. Having one authority would also minimise the risk of overlapping regulation, as well as continuity at the interface between related areas, for example embryo research and cell therapies. RATE would also achieve savings through increased efficiency and effectiveness.

16. Having taken due account of the evidence presented to the Committee, the Government accepts the recommendation to reconsider the proposal to establish RATE. The Government will therefore amend the Bill to drop the proposal for RATE. We will, however, bring in certain provisions for the HFEA that would have been applied to RATE. These include provisions to allow HFEA members to delegate functions to HFEA staff and, with the necessary safeguards, for powers to delegate or contract out functions outside the authority.

17. In accepting the Committee's recommendation, the Government will be looking at the scope, even without a full legal merger, for the two authorities to streamline regulation, for instance through sharing support functions. The Government will be working with the HFEA and HTA on this.²⁵

2. The Bill in the Lords

Legislation was brought to the House of Lords, following a change in the proposed title, in the *Human Fertilisation and Embryology Bill*. [Human Fertilisation and Embryology Bill Paper](#), produced by the House of Lords Library, describes the Bill as it entered that House.

The Bill is in three Parts. Part 1 contains amendments to the HFE Act to take account of recent scientific advances, Part 2 deals with the determination of the parenthood of a child born with the aid of assisted reproductive technologies, and Part 3 makes miscellaneous and general provision. These are briefly summarised in the Explanatory Notes to the Bill.

Part 1

12. Part 1 (including Schedules 1 to 5) makes a range of amendments to the 1990 Act to take account of scientific developments, to reflect changes in social attitudes and to update the HFEA's ability to regulate according to principles of better regulation.

13. To assist the reader of the Bill, the Department of Health has produced an illustrative consolidated text of the 1990 Act as amended. This is available on the Department of Health website and in hard copy. This includes amendments made by the 2007 Regulations and shows the effect of the amendments made by the Bill. The text has no official status.²⁶

²⁵ Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill, CM 7209 8 October 2007

²⁶ [Human Fertilisation and Embryology Act 1990 - an illustrative text](#)

Part 2

14. Part 2 replaces existing provision under the 1990 Act to determine legal parenthood for future cases involving assisted reproduction. The Bill introduces a new concept of parenthood for a mother's female partner in certain circumstances, making equivalent provision to that for opposite sex couples.

15. The 1990 Act currently provides that where an unmarried couple are "treated together" in a licensed clinic using donated sperm, the male partner will be regarded as the father of any child born as a result. "Treated together" in this context is a somewhat loose concept. Part 2 makes provision that both the prospective mother and the man (or in the case of persons in a same-sex relationship, the woman) who is intended to be the second parent of the child must consent in writing to what is intended.

16. Part 2 also makes provision in relation to parenthood in respect of children born after a surrogacy arrangement, which is intended to put same sex couples and unmarried opposite sex couples in the same position as married couples.

Part 3

17. Part 3 of the Bill contains amendments to the Surrogacy Arrangements Act 1985, miscellaneous provisions and general provisions about order and regulation-making powers, powers to make consequential and transitional provisions, and commencement.²⁷

Copies of the Bill at all stages and Explanatory Notes are available [online](#), including the most recent version of the [Bill as it entered the Commons](#) on February 5 2008.

It was debated on the following occasions.

- First Reading: November 8 2007 [[HL Bill 6](#)]
- Second Reading: [November 19 2007](#) (debate adjourned)
 - Resumption of Second Reading: [November 21 2007](#)
- Grand Committee:
 - 1st day: [December 3 2007](#)
 - 2nd day: [December 4 2007](#)
 - 3rd day: [December 10 2007](#)
 - 4th day: [December 12 2007](#)
- Report Stage:
 - 1st day: [January 15 2008](#)
 - 2nd day: [January 21 2008](#)
 - 3rd day: [January 28 2008](#)
- Bill as amended: [HL Bill 25](#)
- Third Reading: [February 4 2008](#)
 - Resumption of Third Reading: [February 4 2008](#)

²⁷ [Explanatory Notes to the Human Fertilisation and Embryology Bill](#)

a. **Summary of amendments passed in the Lords**

The Bill passed through the Lords mostly unchanged though two notable Government amendments were passed.

- The term “inter-species embryos”, which was used to describe human/animal hybrid embryos, was replaced by “human admixed embryos” throughout the Bill. This is detailed in section III D 3 of this paper.
- The Bill removes the requirement of a doctor to consider the need of a child for a father before fertility treatment is undertaken. An amendment now requires the need for supportive parenting to be considered in its place (see section III F of this paper).

3. **Free Votes in the Commons**

Members from all sides of the House have been calling for free votes on all sections of the Bill. In particular, pressure from Catholic Labour Members, calling for a free vote, was reported in the press.²⁸ On March 25 the Prime Minister announced there would be free votes for Labour MPs on the following areas of the Bill:

- Preventing fertility clinics from refusing treatment to single women and lesbians (see section III F 1)
- Creating a “saviour sibling” with the correct tissue match to save a sick brother or sister (see section III B).
- Creating hybrid animal/human embryos to aid stem cell research (see section III D 3).

Andrew Lansley, the Shadow Health Secretary has announced that Conservative Members will be allowed a free vote on the entire Bill.²⁹ A free vote has also been reported for Liberal Democrat Members.³⁰

III **General overview of issues raised by the Bill**

A. **Regulation and the role of the HFEA**

The Government described the broad role of the HFEA in its White Paper, *Review of the Human Fertilisation and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, dated 14 December 2006.³¹

²⁸ BBC website, [Labour MPs may rebel over embryos](#), 21 March 2008.

²⁹ Conservative Party, [Brown still dithering over free vote on Embryology Bill](#), 25 March 2008

³⁰ Religion doesn't rule in this clash of moral universes, *Guardian*, 25 March 2008

³¹ White Paper : [Review of the Human Fertilisation and Embryology Act: proposals for revised legislation \(including establishment of the Regulatory Authority for Tissue and Embryos\)](#), 14 December 2006

The Government proposes that the current model of regulation, whereby Parliament sets the prohibitions and parameters within which a statutory authority licenses activities, should continue

The HFE Act (sections 8-10) defines the general functions of the HFEA, its audit and accounting requirements, how it reports to the Secretary of State and how it operates its licensing function. The HFEA's members are appointed by the Secretary of State for Health. The HFE Act requires that the Chair, Deputy Chair and at least half of the HFEA Members are neither doctors nor scientists involved in human embryo research or providing infertility treatment. HFEA Members bring to the HFEA a broad range of expertise, from medicine to law and religion to philosophy.

The HFEA's purpose is:

to assure patients and the wider public that research and treatment undertaken in the field of assisted reproduction is conducted to the highest standards, and within a robust ethical framework.³²

The functions of the HFEA are:

- To licence and monitor fertility clinics that carry out in vitro fertilisation (IVF) and donor insemination;
- To license and monitor centres undertaking human embryo research;
- To license and monitor the storage of gametes and embryos;
- To produce a Code of Practice which gives guidelines to clinics about the proper conduct of HFEA licensed activities;
- To maintain a formal register of information about donors, fertility treatments and children born as a result of those treatments;
- To provide relevant advice and information to patients, donors and clinics;
- To review information about human embryos, the provision of treatment services and activities governed by the HFE Act; and
- To monitor any subsequent developments in this area and where appropriate, advise the Secretary of State for Health on developments in these fields.³³

The HFEA does not however regulate all areas of infertility treatment or get involved in funding for treatment. The HFEA website states categorically the areas that it does not cover:

It is not a pressure group
It does not regulate all infertility treatments
It is not an ombudsman
It is not involved in funding for treatment
It is not a research body

³² [Human Fertilisation and Embryology Authority Corporate Plan 2004-2009](#), March 2004

³³ HFEA webpage: [FAQ's about the HFEA](#) [on 2 May 2008]

The Joint Committee on the draft Bill considered the role of the HFEA at length, and considered whether IVF really needed the regulation it currently has, considering how much more common it now is as a medical treatment.³⁴

(3) Regulation of treatment

99. There was a range of opinion on whether there was still a need for close regulation of treatment including the requirement to keep records. A number of witnesses, such as Hugh Whittall, Director of the Nuffield Council on Bioethics, agreed that IVF treatment was now “more or less routine”. (Q 5)³⁵ Dr Gillian Lockwood agreed that, in the early days of IVF, the public were concerned that “frightening things were going on”, but “Now we know that is not the case, and a lot of the information that we have to collect and send on to the HFEA is of no value at all to patients or to science or to clinicians.” (Q 428)

She and other clinicians like Simon Fishel were concerned at the “quite remarkable” regulatory burden on staff. (Q 450) Simon Fishel was in favour of a regulatory structure, but he did call for the regulatory process to be streamlined, so that the HFEA only dealt with issues like outcome statistics, personnel review, data on incidents and alerts, public and patient complaints, the maintenance of the register, and “trimmed down” licensing. (Ev85)

100. However, Dr Mark Hamilton argued that there remained value in regulation in terms of “reassuring the public” and “the element of security that it gives those providing the service that they can say we have been inspected by the regulatory authority and we have reached a certain standard that has been approved by the inspection process”. (Q 375) Angela McNab, Chief Executive of the HFEA, warned that a regulator was still required in a sector dominated by private practice, in order to provide “a very clear system for good, professional, evidence-based standards, for ensuring that those are checked, are validated and that where patients have concerns that there is a very clear mechanism for addressing those”. (Q 174) Sir Liam Donaldson told us that “to deregulate in this field would be a bit of a disaster, and the reason I say that is that I think we have a duty to the welfare of patients.” (Q 230)

The Department of Health classifies the HFEA as a body at arm’s length to Government and while Ministers oversee the performance of the organisation, they do not intervene in the policy decisions made by the HFEA.

The HFEA *Corporate Plan 2004-2009* explains how the context in which the HFEA works has evolved:

In the first decade after the passage of the HFE Act, the HFEA established a strong national and international reputation as a regulator of assisted reproductive technology (ART). It played a prominent role in leading and informing public debate about increasingly complex, and sometimes

³⁴ Joint Committee on the Human Tissue and Embryos (Draft) Bill, [Human Tissue and Embryos \(Draft\) Bill Report](#), 1 August 2007 HL 169-I/HC630-1 2006-07

³⁵ See also QQ6, 928

controversial, scientific and ethical issues. Since 1991, however, the environment in which the HFEA works has changed significantly.

Scientific and clinical developments, changes in public expectations and Government policies are making increasing and complex demands on the HFEA. There have been significant increases in the numbers of people seeking information and receiving treatment, as well as major changes in the treatment and research activities regulated by the HFEA. In order to meet these challenges, the HFEA has a duty continuously to modernise both how it works, and how it communicates with the public and key interests.³⁶

Since its inception, reaction to the HFEA has been mixed. In October 2000 the *Second Quinquennial Review of the Human Fertilisation and Embryology Authority* Report to UK Health Ministers, made recommendations for change but gave a positive impression overall of the work of the HFEA:

We have no doubt that the functions of the HFEA need to be maintained for the foreseeable future. Indeed, it has been made clear to us that, with the advances in medicine in this particular speciality, not least in genetics, the need for an independent, statutory body is even more relevant and important than when it was established. [...] This view reflects the current mood of the medical profession at large about the need for clinical governance in its various forms. Indeed, many correspondents commented on the desirability and helpful nature of having an objective and well-defined framework within which to operate.

Later in this report, we comment and make recommendations or suggest changes to the way the Authority operates. But these recommendations and suggestions are not, in themselves, radical enough to call into question the fundamental role of the Authority [...] ³⁷

In February 2002, the House of Lords Select Committee on Stem Cell Research praised the role of the regulator and concluded that:

The HFEA's role is crucial to the effective regulation of research on human embryos and the maintenance of public confidence in the regulatory regime.³⁸

Later that year however in July 2002, the House of Commons Science and Technology Committee highlighted some of the problems:

We note that in the year 2000-01 the HFEA missed its targets for licence renewal (for both treatment and research) by some margin, especially for research licences, though we recognise the problems it has had with high staff turnover. Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy.

³⁶ *Human Fertilisation and Embryology Authority Corporate Plan 2004-2009*, March 2004, para 4.1

³⁷ [Second Quinquennial Review of the Human Fertilisation and Embryology Authority](#), Report to UK Health Ministers, October 2000, para 3.3 – 3.4

³⁸ House of Lords Committee on Stem Cell Research, *Stem Cell Research*, 27 February 2002, HL 83

The HFEA's communication strategy seems to be focused on licensees and patients. While this may be in part because of a lack of resources, the HFEA does not appear to have made much effort to communicate more widely, yet the public has a legitimate interest in its work and administration. Until recently, the HFEA's website reflected poorly on the importance it attached to transparency and accessibility.³⁹

In March 2004 the House of Commons Science and Technology Committee announced its terms of reference for an inquiry into *Human Reproductive Technology and the Law* which involved intensive scrutiny of the HFE Act and the HFEA. The Committee reported in March 2005 and concluded that the HFE Act and the HFEA were effectively out of date:

We propose that the current regulatory model, which provides the HFEA with a large amount of policymaking flexibility, should be replaced with a system which devolves clinical decision making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight.

[...]Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety.⁴⁰

In December 2004 the *Guardian* quoted Lord Robert Winston, Professor of Fertility Studies at Imperial College, London:

“The Human Fertilisation and Embryology Authority (HFEA) ought to be abolished and replaced by a more flexible regime.

[we need] a more efficient body which doesn't inhibit research, which has a better consultation process with the public and which has a much more adequate inspection process. It is time for Parliament to revise what is happening.”⁴¹

In contrast however, the HFEA's international reputation has been commended by organisations such as the British Medical Association (BMA). In oral evidence to the Joint Committee on the draft Bill in June 2007, Dr Vivienne Nathanson, Director of Professional Activities, BMA said:

The evidence is that internationally the reputation of the UK related to the HFEA is very, very strong. [...] Nobody believes that it is perfect but I think that the attitude of the public internationally is that people wish that they had a regulatory agency which they would understand and understand its rules.⁴²

³⁹ House of Commons Science and Technology Committee, [Developments in Human Genetics and Embryology](#), 18 July 2002, HC 791 2002-03

⁴⁰ House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law*, 24 March 2005, HC 7 2004-05, chapter 9

⁴¹ “Axe IVF watchdog, says fertility expert: Robert Winston wants ‘out of date’ authority replaced,” *The Guardian*, 11 December 2004

⁴² Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill*, 1 August 2007, HL 169-1 HC 630-II 2006-07, Q67

1. Register of information

The HFEA has been criticised for not allowing researchers access to information about fertility treatments on its registry:

Much of the research could be undertaken using anonymous data and we believe the HFEA should facilitate more follow-up research by allowing bona fide researchers access to anonymous information from the register. Where identifiable data are required then this should be with patient consent. For future treatment cycles, seeking consent to the use of information for research could be incorporated as a routine part of the general consent process by clinics.⁴³

The HFEA's current position on allowing data access is restricted by the HFE Act. Researchers can apply for access to some data, but stringent anonymity criteria can impede its utility. Lord Winston raised the issue of the need to access information during the Lords Committee Stage by providing the following examples:

There is one other issue that concerns me as a research worker. There is growing evidence that in the next decade we are going to understand much more about the complications of genetics. There is a growing focus on an area of genetics called epigenetics, which is where the DNA does not change but the way that the DNA function is capable of changing because of its environment. The environment at the beginning of development is extremely important. For example, we now know that very early environmental influences in the first few days of a mammal's life can radically alter its phenotype—that is, how it becomes later on in life. The classic example was originally the low birth-weight baby which, when it became 50 or 60, sometimes had a much higher risk of hypertension, heart disease, stroke and so on. But there almost certainly are much more subtle epigenetic effects than this in the human, though at the moment there are very few conditions that one can identify. There are one or two.

There are specific things which are done to human embryos in culture which might produce unpredictable epigenetic effects. Those include embryo freezing. We have evidence in my own laboratory that when human embryos are frozen under certain routine circumstances, gene expression changes; that is, the genes change the protein that they produce, at least only temporarily. One of the genes that we have looked at protects against cancer. I am not suggesting an alarmist reaction to this work, but it was published in a very important peer review journal and was obviously acceptable to that journal. We have to say that there is a need for continuous follow-up for the sorts of thing that we do in in vitro fertilisation over a long period.

Embryo freezing is by no means the only procedure that should be under surveillance. Prolonged culture—where embryos are kept in culture for more than three days, up to five or six days—is a growing trend in in vitro fertilisation at the moment. We know from work in mice that that also may produce anomalies of gene expression under certain circumstances. The third area I can think of

⁴³ Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill*, 1 August 2007, HL 169-1 HC 630-II 2006-07, Ev29

immediately, though there are many others, is changes in the culture in which the embryo is produced.

None of those should prevent us continuing to offer in vitro fertilisation. There is clearly no evidence of major abnormalities as a result of in vitro fertilisation—at least in this country—compared with people who had babies by the other method. When I say “the other method”, I remember my six year-old sitting at the breakfast table once saying to me, “Dad, tell me, are more babies born by the test tube or by the other method?”. In a family like mine it becomes a routine thing. I hope the Committee will forgive the digression.

It is important that we recognise that it should be easier to survey children long-term, keeping proper records of those children if we can, in order to promote research rather than hinder or prevent it. One way of doing that is to avoid the unnecessary restrictions on confidentiality which do no good for the patient and which are now obsolete in terms of treatment. The routine issues of informed consent and the normal confidentiality that exist with virtually every other medical procedure should suffice for in vitro fertilisation as well.⁴⁴

a. *The Bill*

Clause 25 of the Bill enables the Secretary of State to make provision for the disclosure of information falling within Section 31 of the HFE Act for research purposes. Information can be disclosed for the purposes of medical research where the Secretary of State considers it necessary or expedient in the public interest or in the interests of improving patient care. It will also amend exceptions to the prohibition on disclosure which are currently listed in section 33 of the HFE Act.

B. Embryo screening and disability

Pre-implantation genetic diagnosis (PIGD) and pre-implantation tissue typing are two different techniques. They are both types of pre-implantation diagnosis (PID) which are used individually or in combination to check embryos for disease. Establishing the presence of diseases or characteristics in the embryo provides the opportunity to choose an embryo for implantation.

A “saviour sibling” is one which is able to be used to provide some treatment for an existing child. The most common example of this is parents who have one child suffering from a condition which needs a bone marrow transplant. Currently this would involve using in vitro fertilization to create several embryos, then checking the genetic make up of those embryos and implanting one with the desired (or without the undesired) characteristics. Case law has also established that the HFEA could issue a licence for PID in an individual case (*Qunitavalle vs HFEA*).

⁴⁴ HL Deb 12 December 2007 c250

Several arguments are commonly raised on this issue.⁴⁵

- The status of the embryo. If an embryo is selected with a particular characteristic it is likely that other embryos (with undesirable characteristics) will be discarded. There is concern that a child that [is] created and born to treat another child may be stigmatised or disadvantaged by being seen as a commodity rather than a person.
- Donation of tissue from babies requires the parents to make a decision in the best interests of the child. Where two children of the same parents have conflicting best interests, the issue of consent becomes more difficult.
- When might it be appropriate to select against undesirable (or for desirable) characteristics, there are question of what diseases or conditions are serious “enough” to be removed, and which characteristics could be selected and for which reason.

This final point has received most media attention as disability rights campaigners have raised concerns about the Bill. The British Deaf Association explains one of its major concerns.

Impact of genetic screening and selection against deafness and the negative effect on the remaining population of deaf people. By codifying into law a preference for selecting embryos that are genetically associated with hearing, potential deaf people who would have otherwise been born will not have an opportunity to exist. Over time this is likely to bring about a less diverse society, including the potential for the decline or demise of BSL [British Sign Language]. Smaller numbers of deaf people overall may result in less communication access and fewer services offered to this population.⁴⁶

Debate has recently been extended to include the possibility of selecting for traits that many would consider undesirable. A number of press articles have commented on the possibility of parents selecting for deaf children. The following from the Sunday Telegraph is an example:

Deaf campaigners claim that, although the vast majority of deaf parents would want a child who had normal hearing, some might prefer to create a child who was also deaf and so better able to fit in with their family.

They argue that the proposed legislation is discriminatory because it gives parents the right to create "designer babies" free from inherited genetic conditions while banning disabled couples from deliberately creating a baby who shares their disability. Doctors, however, strongly oppose any plans to allow the creation of deaf babies.

⁴⁵ *Saviour Siblings and the Discretionary Power of the HFEA* Sheldon Med Law Rev.2005; 13: 403-411

⁴⁶ British Deaf Association, [Draft Response to Human Fertilisation and Embryology Bill \(Amended 4/12/07\)](#)

The issue first came under the spotlight six years ago in America, when it emerged that a deaf couple had sought out a sperm donor with a family history of deafness. After the anger caused by that case, officials singled out deafness as being a condition that would be covered by the Bill.

Ministers, however, were shocked by the strength of opposition from members of the deaf community. Campaigners now believe the removal of the reference to deafness signals a softening of the Government's position.

They now hope that MPs will be able to amend the Bill when it is debated so that the clause banning the creation of disabled children will be dropped entirely. This, they say, would grant deaf parents equal rights with hearing parents.

Anna Middleton, a genetics counsellor involved in the campaign to change the clause, said: "It is encouraging that our debate with the Department of Health has had this impact."

Professor Peter Braude, director of the country's leading centre for pre-implantation genetic diagnosis at Guy's and St Thomas' Hospital in London, said: "I have serious concerns about deliberately selecting an embryo for deafness. This is the same as taking a normal child and deliberately making it deaf so that it can fit in with a community.

"I don't see how that can be acceptable."⁴⁷

A subsequent letter from the Health Minister Dawn Primarolo to the Sunday Telegraph stated that the Government had no plans to legalise this practice.

The embryo testing provisions in the Human Fertilisation and Embryology Bill are to avoid serious medical conditions or disabilities, not to create babies with desired characteristics or traits, such as deafness (News, April 13). The Government has agreed to remove references singling out deafness from the explanatory notes of this clause, but has no plans to make amendments to the embryo testing and selection provisions in the Bill.⁴⁸

1. The Bill

a. Saviour Siblings

The *Human Tissue and Embryos (Draft) Bill* permitted the practice of screening embryos for saviour siblings to help with life threatening disease. However the Joint Committee considered this too narrow.⁴⁹ As a result the Bill, as introduced to the Lords, used the word "serious."

The following answer to a parliamentary question goes some way to explaining what is meant by the term "serious" and includes the Joint Committee's recommendation.⁵⁰

⁴⁷ Couples could win right to select deaf baby in embryo Bill change, *The Sunday Telegraph*, 13 April 2008

⁴⁸ Embryology change, *The Sunday Telegraph*, 20 April 2008

⁴⁹ Joint Committee on the Human Tissue and Embryos (Draft) Bill, [Human Tissue and Embryos \(Draft\) Bill Report](#), 1 August 2007 HL 169-II/HC630-II 2006-07

⁵⁰ HL Deb 10 January 2008 c219WA

Lord Patten asked Her Majesty's Government:

Whether they will define the word “serious” where it is used in the Human Fertilisation and Embryology Bill in relation to its provisions permitting organs to be removed from a saviour sibling child; and how this differs from the current definition permitting the removal of organs only in life-threatening circumstances.

Lord Darzi of Denham: The Human Fertilisation and Embryology Bill includes five purposes for which embryos can be tested. One of these relates to tissue typing—where embryos are tested to see whether they have histocompatible tissue where cord blood, bone marrow or other tissue could be used in the treatment of a sick older sibling where the sibling is suffering from a serious medical condition.

The draft Human Fertilisation and Embryology Bill, then called the Human Tissue and Embryos Bill, was published for scrutiny by a Joint Committee of both Houses. In the draft Bill, the provision required that the child be suffering from a life-threatening condition. The committee recommended that this be changed to a serious condition. The report from the Joint Committee on the Human Tissue and Embryo Bill said:

“We recognise that this is a delicate area. However, given the Government's apparent acceptance of the principle of selecting for saviour siblings' we do not understand why the practice is limited to 'life-threatening' conditions capable of treatment using umbilical cord blood cells. We recommend that the draft Bill be amended to substitute 'serious' for 'life-threatening'”.

The Bill introduced into the House of Lords in November reflected that recommendation.

Clause 11 of the Bill introduces Schedule 2 to the Bill which amends Schedule 2 to the HFE Act by adding new paragraphs 1ZA to 1ZC which relate to embryo testing. The Explanatory Notes to the Bill described the circumstances under which tissue typing would be allowed.⁵¹

54. Paragraph 1ZA(1)(d) is concerned with “tissue typing” – establishing whether the embryo would result in a child whose tissue was compatible with that of an existing child (the sibling). Embryo testing for this purpose could be licensed where the sibling suffers from a serious medical condition that could be treated with matched tissue from the sibling including stem cells found in umbilical cord blood and bone marrow.

A number of amendments were tabled in the Lords to restrict the term “serious”. This included an amendment tabled by Earl Howe in response to which the Minister provided some assurance that subsequent guidance would be produced on how the term should be defined:

Baroness Royall of Blaisdon: My Lords, forgive me for interrupting the noble Earl, but I did give an assurance that we would be able to do something in

⁵¹ [Human Fertilisation and Embryology Bill: Explanatory Notes](#)

guidance. I could not give an assurance that we could include something in the Bill, but I give my wholehearted assurance that we will put something in guidance to that effect.

Baroness Deech: My Lords, before the Minister sits down, can she clarify the extent of the Government's powers to put something in guidance? I recollect that it would be within the discretion of the HFEA, and I am not sure that there could be a guarantee that something would be in guidance. I may be wrong and that when draft guidance goes to the department something can be inserted, but I am not sure that I recollect that.

Baroness Royall of Blaisdon: My Lords, I understand that we have given an undertaking in relation to counselling and information, and that there will be duties on the HFEA in terms of guidance. I think that it will be the same here, and we will ensure that there is a duty on the HFEA to adhere to this guidance. If I am incorrect, I will notify noble Lords as soon as possible.

Lord Slynn of Hadley: My Lords, is it the Minister's intention that the "something" should be nearer to what has been proposed by the noble Earl, Lord Howe, or whether it will be very different and even more vague than the term, "serious"?

Baroness Royall of Blaisdon: My Lords, we would work the basis of the wording of the amendment tabled by the noble Earl.⁵² However, we would have to take into consideration the views expressed by noble and learned Lords.

Earl Ferrers: My Lords, does the noble Baroness agree that if something is in guidance it is just that—guidance—and not an instruction? Therefore, the recipient body would look at the guidance but would not necessarily feel obliged to stand by it?

Baroness Royall of Blaisdon: My Lords, guidance is guidance, yet the code to which the HFEA must adhere needs Secretary of State approval. As I understand it, that would be statutory guidance.⁵³

b. Other Screening

Currently the HFEA does not allow for the selection of the sex of an embryo except for medical reasons; for example if there is a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness or other serious medical condition such as Duchenne Muscular Dystrophy or where there is a strong family history of breast cancer. This position will be maintained in the Bill. Paragraph 4 of Schedule 2 to the Bill will prevent sex selection for non-medical reasons.

The Bill will also ensure that embryos can be tested in order to resolve any uncertainty that has arisen as to the identity of the persons who provided the gametes used to create the embryo.

⁵² Earl Howe's amendment would have described the term "serious" as meaning life-threatening or impairing severely the quality of life of a person with the disability, illness or condition.

⁵³ HL Deb 21 January 2008 c32

C. IVF

IVF is a term used in general parlance to describe a collection of techniques and procedures that are used to make babies. The term “Assisted reproductive technologies” (ART) is more accurate, and is increasingly being used. It correctly covers many techniques that assist technology that are not strictly in vitro fertilisation. Technically, IVF means the addition of sperm cells to egg cells outside the body, and the subsequent creation of an embryo.

In vitro fertilisation (IVF)

What is it? Eggs and sperm are collected and fertilised in the laboratory before the resulting embryo is transferred to the womb. The woman takes fertility drugs to stimulate the production of eggs. Once these are mature, they're collected by ultrasound guidance. The man produces a sperm sample, which is prepared before being put with the eggs in a Petri dish and left for a few days to see if fertilisation takes place. A resulting healthy embryo is placed in the womb using a catheter (a very fine needle or probe). Any remaining embryos that are suitable for freezing may be stored for future use. The sperm and/or eggs used may be the couple's own or donated.

This parliamentary question shows how many embryos are created in the course of IVF treatment⁵⁴

<i>Total number of in vitro fertilisation (IVF) treatment cycles, embryos created and treatments resulting in live births 1991 to 2004⁽¹⁾</i>							
	<i>Treatments involving fresh (non-frozen) embryos</i>			<i>Treatments involving frozen embryos⁽²⁾</i>		<i>Non-treatment⁽³⁾</i>	
<i>Year (calendar)</i>	<i>Treatment cycles</i>	<i>Embryos created</i>	<i>Treatment cycles with live birth outcome</i>	<i>Treatment cycles</i>	<i>Treatment cycles with live birth outcome</i>	<i>Non-treatment cycles</i>	<i>Embryos created</i>
1991	5,948	26,543	822	696	105	—	—
1992	16,022	75,456	2,114	2,233	252	—	—
1993	18,860	92,809	2,757	2,939	376	—	—
1994	21,345	106,425	3,144	3,491	402	—	—
1995	24,753	126,078	3,856	4,548	542	—	—
1996	27,428	148,691	4,765	5,994	691	—	—
1997	27,811	146,066	4,933	6,178	707	—	—
1998	29,078	163,206	5,584	6,445	781	—	—
1999	28,212	163,840	5,833	6,602	844	804	575

⁵⁴ HC Deb 14 May 2007 c594W

2000	28,591	170,406	5,981	6,877	908	976	728
2001	28,812	176,947	6,171	7,415	1,017	898	603
2002	29,781	178,794	6,708	7,639	1,070	756	724
2003	30,069	179,906	6,924	7,449	1,178	713	968
2004	32,141	185,409	7,123	7,956	1,167	694	1,038

⁽¹⁾2004 is the most recent year for which information is available.

⁽²⁾Embryos used in these cycles may have been created in previous years as part of fresh treatment cycles.

⁽³⁾These are IVF cycles that, although started, did not progress to embryo transfer. These embryos may have been used in a patient's later frozen treatment cycles or for embryo donation. No data is held for years 1991-1998.

Source: HFEA

a. Availability of IVF treatment on the NHS

The availability of IVF treatment services involves the National Institute for Health and Clinical Excellence (NICE).

NICE issued guidance on fertility treatment, including in vitro fertilisation (IVF), on 25 February 2004. The full guidance is available on NICE's website together with other relevant documents.⁵⁵ According to NICE's summary, key recommendations in the guidelines include:

- Screening all women for chlamydia before they undergo procedures to check if their fallopian tubes are blocked.
- Offering women who do not have any history of problems with their fallopian tubes an x-ray to see if their tubes are blocked, rather than an invasive procedure.
- Offering six cycles of intra-uterine insemination (IUI) to couples with:
 - Slightly abnormal sperm count,
 - Mild endometriosis, or
 - Unexplained fertility problems.
- Offering 3 cycles of stimulated IVF to couples in which the woman is aged between 23-39 who have an identified cause of their fertility problems or unexplained fertility of at least 3 years.

John Reid, who was Secretary of State for Health at the time that the NICE guidance was issued, confirmed the guidance as Government policy and said that as a first step towards implementation, from April 2005 all PCTs should offer at least one cycle of IVF to people who were eligible. He also added an additional priority of the Government's when he said that he would be asking local PCTs to give priority to couples who did not

⁵⁵ NICE webpage: [Fertility](#) [on 2 May 2008]

have any children living with them.⁵⁶ This “social condition” is additional to the original NICE guidance.

Some types of NICE guidance, known as technology appraisals, have to be financed by Primary Care Trusts (PCTs) but NICE’s guidance on fertility is not one of these; it is known as a clinical guideline. Its implementation is a matter for government and the NHS at a local level and it has been clear from the start that the guidance would be phased in.

Questions about Primary Care Trusts that are not implementing the policy have been raised on several occasions in Parliament. On 24 July 2007 the Government issued a press notice about action that it was taking to encourage wider implementation of the NICE guidelines. This said:

Public Health Minister Dawn Primarolo today outlined new measures to help the NHS improve childless couples' access to IVF treatment.

Following on from the NICE guideline on fertility, published in 2004, which recommended up to three cycles of IVF for eligible patients, the Department of Health is working with leading infertility patient group Infertility Network UK to assist PCTs in giving consideration to fertility treatment and improve access.

This work will include:

- developing, in partnership with the NHS, social access criteria for IVF treatment to ensure a standardised approach across the country for deciding which couples are eligible for treatment;
- producing best practice guidance for PCTs, so that those struggling to provide enough cycles to patients can learn from other PCTs that are successfully implementing the NICE recommendations;
- the Department of Health has also announced that it will begin monitoring IVF provision across the country to help identify where the NHS may need further assistance.

The Department of Health will work with the HFEA to promote costed treatment plans for people seeking IVF in the private sector, through their Code of Practice. This will provide assurance to patients of the cost of their treatment in advance.

With the NICE review of its fertility guidance due next year, the department will liaise with NICE about new research which indicates that the minimal use of drugs in stimulating egg production may be as effective and safer than higher levels of stimulation.

Dawn Primarolo said:

"We recognise that there are local variations in the provision of IVF and that this does cause distress to many childless couples who feel that they are not getting the treatment they need.

⁵⁶ Department of Health Press Notice 2004/0069, [Health Secretary welcomes new fertility guideline](#), 24 February 2004.

"Primary responsibility for implementing NICE guidelines rest with the NHS at local level, but it is important that PCTs are fully aware of the needs of infertility patients when deciding their policies and setting their priorities.

"We want to help PCTs deliver these services and that is why we will be working with Infertility Network UK on ways in which it can work with PCTs to help ensure that fertility patients' voices are heard when decisions about the provision of services are made at local level.

"The project will focus on identifying best practice in the provision of fertility services, and on sharing that best practice between PCTs. In addition to this, the Department of Health will be monitoring IVF provision across the NHS on an on-going basis to see where further assistance maybe needed."⁵⁷

Progress on this work was outlined in answer to a recent parliamentary question:

Chris McCafferty: To ask the Secretary of State for Health what steps he has taken to (a) monitor and (b) encourage the implementation of National Institute for Health and Clinical Excellence guidelines on the assessment and treatment of people with fertility problems; and if he will make a statement. [195007]

Dawn Primarolo: The Department has recently carried out a survey of in vitro fertilisation provision and will publish the results in due course.

We are working with the patient support organisation Infertility Network UK to help primary care trusts (PCTs) share best practice in the provision of fertility services and move to the implementation of the National Institute for Clinical Excellence recommendations. To build on the progress being made we are establishing an expert group to advise the project and consider how to help PCT commissioners.

The Department will be monitoring IVF provision across the National Health Service on an on-going basis to see where further assistance may be needed.⁵⁸

b. Permitted Embryos

Clause 3 of the Bill amends section 3 of the HFE Act, which covers prohibitions connected with embryos. Section 3(2) prohibits the placing in any woman of any embryo other than a permitted embryo. The Explanatory Notes explain what a permitted embryo is:

A permitted embryo is defined as an embryo which has been formed by the fertilisation of a permitted egg by a permitted sperm, whose nuclear or mitochondrial DNA has not been altered and which has not had cells added (except by division of the embryo's own cells). Permitted eggs are defined as eggs produced by or extracted from the ovaries of a woman and permitted sperm as sperm produced by or extracted from the testes of a man. These eggs and

⁵⁷ Department of Health Press Release 2007/0209, [Minister announces extra help for IVF provision](#), 24 July 2007

⁵⁸ HC Deb 25 Mar 2008 c17W

sperm must also not have been subject to any alterations to their nuclear or mitochondrial DNA. This clause ensures embryos created by artificial gametes or genetically modified gametes could not be placed in a woman. Similarly, genetically modified embryos or embryos created by cloning cannot be placed in a woman. This prevents reproductive cloning and supersedes the Human Reproductive Cloning Act 2001.

32. A regulation-making power has been provided under new section 3ZA(5) of the 1990 Act to allow the meaning of permitted eggs and permitted embryos to be extended to include eggs or embryos that have been treated in such a way as specified in regulations to prevent the transmission of serious mitochondrial disease.¹ In the future, it may be possible to create embryos using an affected woman's egg, her partner's sperm and healthy donated mitochondria. This regulation-making power will enable such embryos and eggs to be implanted in a woman if the technology became available and was proven safe. Further provision is made regarding mitochondrial donation in clause 26, which inserts new section 35A into the 1990 Act.

¹Mitochondria are found outside the nucleus of the cell and contain a small amount of DNA. They are involved in energy production and are present in most cells in the body. If a woman's egg is fertilised by sperm the mitochondria from her egg will become the mitochondria for every cell of the embryo formed. Therefore, if a woman has a genetic medical condition associated with her mitochondria, these will be inherited via her eggs.⁵⁹

D. Scientific uses for embryos

The area of science affected by this Bill is concerned with research using human embryos. Embryo research can be broadly divided into two groups; techniques that develop in vitro fertilisation (IVF) and research using embryonic stem cells.

1. Embryonic stem cells

Stem cells are a special type of cell that can reproduce themselves indefinitely. Embryonic stem cells are pluripotent, which means they have the potential to produce cells that can differentiate into a wide variety of different cells. Adult stem cells have already differentiated, so they can only produce one type of cell, and are termed mono (or uni) potent.

This is a general description, and there are exceptions amongst different types of cells. The pluripotency of types of stem cells varies, ranging from embryonic stem cells, which have the most potential to become any sort of cell, through to adult stem cells which are already well differentiated into specific types of cell.

Research into different types of stem cells and their potential to be used as treatments (also known as regenerative medicine) is at different stages. Adult stem cells can be relatively easily obtained from various parts of the body, and so have been researched

⁵⁹ [Explanatory Notes to the Human Fertilisation and Embryology Bill](#)

for some time and some treatments using them are already well established, such as bone marrow transplants for leukaemia.

Embryonic stem cells are at a much earlier stage of research, which is still being conducted at a “basic” level. “Basic science” is that initial research which has to be conducted before applications using that research can be developed. The American Cancer Society defines basic science as:⁶⁰

[...] laboratory studies that are not aimed at specific problems but that provide the necessary knowledge and background for later applied research.

Researchers are identifying the biochemical switches and changes that an embryonic stem cell undergoes as it specialises and keeping these cells alive in a laboratory is itself an area of much research. It is often argued that this basic research is required if scientists are to develop mechanisms for making other cells act like embryonic stem cells and thus reduce the need to use embryos.

The HFEA consultation document provides this outline of the scientists’ use of embryos.

2.1 Since the late 1990s, when the first cloned mammal was created and the first human embryonic stem cells were derived, stem cell science has become an active area of research. Human embryonic stem cells (unspecialised cells which can develop into any of the body’s 200 different cell types) are useful for studying a wide range of diseases in the laboratory. These cells could also, in the future, form the basis of new therapies for currently untreatable conditions such as Alzheimers or Parkinson’s disease.

2.2 To derive stem cells, researchers allow an embryo to grow in the laboratory for five to six days after fertilisation. They then isolate the stem cells, thereby destroying the embryo, and place them in a mixture of nutrients which keep the cells in their unspecialised state.

2.3 One way of studying a particular disease is to create stem cells which contain the same features as a person suffering from the disease. To do this, researchers take a cell (such as a skin cell) from an adult with the disease in question and extract the genetic information (the nucleus) from the cell. They then transfer that genetic information into an egg from which the genetic information has been removed, activating the egg so that it starts to divide. This process is called cell nuclear replacement (CNR), though it is often referred to as cloning.

2.4 The resulting embryo, which is a clone of the adult, is grown in the laboratory for a few days, after which stem cells are isolated. Once in a stable state in the laboratory, the stem cells could be encouraged to specialise into particular cell types, such as brain or pancreatic cells. These cells could provide a model for the disease in question.

2.5 Another purpose of research in which cloned embryos are created, is to understand what happens to the DNA in an adult cell when it is put into an egg

⁶⁰ American Cancer Society: [Glossary Search webpage](#) [on 2 May 2008]

during CNR and transformed into an embryonic state. If this process were understood, it could become possible to take a cell from an adult and to change it into an unspecialised cell which could be used in therapies without first having to make an embryo.

2.6 Where do the eggs used in cell nuclear replacement come from? Some IVF patients donate eggs that they are unable to use in their own treatment (usually because the eggs have failed to fertilise properly). However, scientists seeking to derive stem cells say that they need to use viable eggs in order to create stable stem cell lines. As a result, some UK research programmes are seeking to use viable eggs either from IVF patients or from women who are not patients.

2.7 The main practical difficulty with using donated eggs in CNR research is that it is very difficult to recruit egg donors, largely because donation is a physically demanding process which can, in rare cases, harm the donor's health. As a result, there are long waiting lists for people seeking donor eggs for IVF treatment and research programmes struggle to obtain enough eggs for their work.⁶¹

Possible applications which may come from stem cell research include treatment by transplanting healthy stem cells to replace cells that may have worn out, such as pancreas cells for diabetes and brain cells for Alzheimer's. Further information on stem cell therapies is contained in the Parliamentary Office of Science and Technology (POST) Note, [Regulating Stem Cell Therapies](#).

Stem cells may also be used to cultivate human tissues outside the body so that medicines can be tested in the laboratory before entering human trials. Studying embryonic stem cells may also provide scientists with an opportunity to understand genetic disorders (see section III B).

Further information on the potential benefits of stem cell research is available on the following websites:

[New Scientist](#)

[UK Stem Cell Foundation](#)

[UK Stem Cell Initiative](#)

Information on the regulation of stem cell research in other countries is contained in Appendix 2 of this paper.

a. The Bill

Part 1 of the Bill would amend the HFE Act to take account of a range of scientific developments. Clause 1 redefines the meaning of the terms "embryo" and "gamete". This clarifies the regulatory position of the HFEA and ensures that embryos created by means other than fertilisation and immature gametes (sperm and eggs) are included under the HFEA's regulatory regime.

⁶¹ [HFEA, A consultation on the ethical and social implications of creating human/animal embryos in research, April 2007.](#)

2. Regenerative medicine in the UK

The Government has actively positioned the UK as a world leader in regenerative medicine. Many scientists come to work here from less permissive environments. UK Trade and Investment made the following statement in a recent document *Regenerative medicine in the UK – global leadership*⁶²

...Furthermore, its emergence is timely, because on average people in the developing world are living longer, resulting in a rise in degenerative diseases such as those of the heart, brain and major organs. UK scientists have been involved in regenerative medicine since the outset. The UK's leadership began in the early 1980s when researchers led by Sir Martin Evans at the University of Cambridge isolated mouse embryonic stem cells.

Since then, considerable progress has been made, including the cloning of "Dolly" the sheep at the Roslin Institute, Scotland in the mid-1990s. However, significant scientific and commercial hurdles need to be overcome before regenerative medicine becomes a mainstay of the fight against disease.

As a world leader in regenerative medicine, the UK will play a key role in translating potential into reality.

- Dementia affects one in 20 people over the age of 65 and one in five over 80.
- To date around US\$350 million has been invested in UK stem cell research by the public sector and charities.
- UK Government organisation, the Department of Trade & Industry (DTI), has invested over US\$40 million in initiatives to promote regenerative medicine.

A parliamentary question recently outlined the Government's position on this:

Mr. Hayes: To ask the Secretary of State for Health what her position is on EU level controls on stem cell research; and if she will make a statement. [90533]

Andy Burnham: Control of stem cell research across the European Union is carried out at member state level in accordance with the laws of each individual state, a position which the Government support. The United Kingdom (UK) is a global leader in stem cell research. In order to maintain this lead, the Government have allocated an additional £50 million to this work, bringing total investment up to £100 million, for stem cell research between 2006 to 2008. In addition, UK researchers may apply for EU (FP7) funding if the research meets the necessary criteria.⁶³

3. Animal human hybrids

The area of the Bill that has attracted the most media attention relates to provisions that will allow scientists to create hybrid embryos by combining material from animal and

⁶² UK Trade and Investment: [Regenerative medicine in the UK: Fighting disease with world class science](#), June 2007

⁶³ HC Deb 7 November 2006 c1316W

human cells. There are several distinct types of animal human embryo, as this excerpt from the Explanatory Notes to the Bill explains⁶⁴

- Cytoplasmic hybrids (Cybrids): embryos created by techniques used in cloning, using human gametes or cells and animal eggs. The embryos would be mostly human except for the presence of animal mitochondria.
- Human-animal hybrid embryos: any other embryo created using a human egg and the sperm of an animal, or an animal egg and a human sperm or by combining a pro-nucleus of an animal with a human pro-nucleus.
- Human transgenic embryos: embryos created by the introduction of animal DNA into one or more cells of the embryo.
- Human-animal chimeras: human embryos, altered by the addition of one or more cells from an animal.

The technique to create cytoplasmic hybrids is known as somatic cell nuclear transfer (SCNT). Research using SCNT has already been used to create hybrid embryos and is also used in therapeutic cloning.

The Government published its proposals for revision of the *Human Fertilisation and Embryology Act* (HFE Act) in December 2006. These included proposals to clarify policy on the creation of human-animal hybrid or chimera embryos. The White Paper explained that the Government had found the law too narrow in that it did not accommodate processes of embryo creation that have been developed since the HFE Act was passed. Such processes could be used to create embryos combining human and animal material. The Government initially proposed to clarify the extent to which the law applies to such entities while also prohibiting their creation. The following from the White Paper explains:

Embryos combining human and non-human material

2.81 At present, the HFE Act allows the mixing of human and animal gametes (under licence) only for the purpose of testing the fertility or normality of sperm, provided that the result of the mixed gametes is destroyed when the test is complete (and definitely no later than the two cell stage). This restriction reflected public concerns about the possibilities of creating “hybrid” embryos (for example, by the fertilisation of a human egg with the sperm of another species), or “chimeras” (for example, by fusing the cells of a human embryo with cells from the embryo of another species).

2.82 The law does not, however, refer to more novel processes of embryo creation that have been developed since the Act was passed, and which, in theory, could be used to create embryos combining human and animal material. The extent to which the law and regulation would apply to embryos created in these circumstances is not sufficiently clear, although the law would clearly prevent such embryos being placed in a woman. In some circumstances the embryo created could be, genetically speaking, almost entirely human and therefore could fall within the regulatory controls applicable to human embryos.

[...]

The Government intends to put this matter to Parliament for further consideration.

Revised legislation will clarify the extent to which the law and regulation

⁶⁴ [Explanatory Notes to the Human Fertilisation and Embryology Bill](#)

applies to embryos combining human and animal material. The Government will propose that the creation of hybrid and chimera embryos *in vitro*, should not be allowed. However, the Government also proposes that the law will contain a power enabling regulations to set out circumstances in which the creation of hybrid and chimera embryos *in vitro* may in future be allowed under licence, for research purposes only.⁶⁵

In April 2007 the House of Commons Science and Technology Committee responded to these proposals by calling for greater freedom particularly in the creation of cytoplasmic hybrid embryos for research. In the meantime the HFEA received two applications (see below) to conduct research work using such embryos.

We have conducted this inquiry in response to the publication of Government proposals to prohibit the creation of human-animal chimera or hybrid embryos for research for the time being. We have also taken account of recent applications from researchers for licences to create human-animal cytoplasmic hybrid embryos for research.

There have been significant developments in science and medicine since the passing of the Human Fertilisation and Embryology Act in 1990, and we recognise the need for revised legislation in this area of research. We believe that public confidence in this area of research must be encouraged and that the Government should ensure wider public understanding in this area through increased education and dialogue. We find this of particular importance in respect of the sincere ethical and moral concerns associated with the creation of human-animal chimera or hybrid embryos for research.

We find that the creation of human-animal chimera or hybrid embryos, and specifically cytoplasmic hybrid embryos, is necessary for research. However, we maintain the view of the previous Science and Technology Select Committee that development of human-animal chimera or hybrid embryos past the 14-day stage should be prohibited and that a prohibition should be put in place on the implantation of human-animal chimera or hybrid embryos in a woman.

We are critical of the Human Fertilisation and Embryology Authority for delaying assessment of applications for licences to create cytoplasmic hybrid embryos for research. It is the role of HFEA to make judgement in areas considered within the spirit of the HFE Act and we find delay of assessment of these applications by HFEA inappropriate once the Authority had established that such research is within its remit.

We find the Government proposals prohibitive, notwithstanding the provision of powers to allow future regulation in this area at an unspecified date. Some research practices should be permitted under licence immediately. We recommend that the Government build upon its previous, successful, record through regulation of embryo research and we propose mechanisms for legislation and regulation of the creation of human-animal chimera or hybrid embryos for research. We are critical of the Government for not clearly setting out

⁶⁵ Department of Health, [Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation \(including establishment of the Regulatory Authority for Tissue and Embryos\)](#), December 2006

the areas of research practice intended to fall under the proposed legislation and suggest that greater attention should be paid to implications of the proposals for current research practice and the UK research base.⁶⁶

In April 2007 the HFEA consulted on licensing for all types of human animal admixed embryos, a response, in part, to the recent applications. The consultation involved a number of public events, an opinion poll of 2,000 UK residents and an online form. 810 people responded to the written consultation, the majority of whom were individuals. The [Report](#) on the consultation is available online and contains a full record of the results. These are summarised in the accompanying press release. This also notes the decisions of the HFEA on how to proceed.

"Having looked at all the evidence the Authority has decided that there is no fundamental reason to prevent cytoplasmic hybrid research. However, public opinion is very finely divided with people generally opposed to this research unless it is tightly regulated and it is likely to lead to scientific or medical advancements.

"This is not a total green light for cytoplasmic hybrid research, but recognition that this area of research can, with caution and careful scrutiny, be permitted. Individual research teams should be able to undertake research projects involving the creation of cytoplasmic hybrid embryos if they can demonstrate, to the satisfaction of an HFEA licence committee, that their planned research project is both necessary and desirable. They must also meet the overall standards required by the HFEA for any embryo research.

"Having looked at the principles behind this kind of research, an HFEA licence committee will now look at the details of the two specific research applications that were submitted earlier this year. We would hope to have a decision on both applications in November.

"In general, people who do not fundamentally oppose embryo research are prepared to accept that human animal research may have some value. But there is a clear demand from people to know more about what researchers are doing and their plans for future work, highlighting a need for better communication about science and research from both the scientific community and ourselves as regulator. In the coming months we will be looking to see how this can be delivered.

"In terms of other kinds of hybrid and chimera research, it became very clear that not only did the scientific community not wish to perform such research at present but that the prospect was so distant that they could not envisage what form this research would possibly take in the future.

"The Authority felt it would be completely wrong to make a decision on broader hybrid and chimera research without an adequate evidence base. However, the

⁶⁶ Science and Technology Committee, [Government proposals for the regulation of hybrid and chimera embryos](#), 5 April 2007, HC 272-II 2006-07

HFEA will continue to monitor the potential for this wider research and any emerging evidence through its 'horizon scanning' programme."⁶⁷

a. The recent HFEA decisions

In November 2006, the HFEA received applications from two different research teams for a licence to derive stem cells from human embryos, created from animal eggs instead of human eggs. On 17 January 2008, a committee of the HFEA granted licences to the two groups. One of their main considerations was whether this basic science could be allowed to go ahead within the current provisions of the law.

11. The Committee considered whether the project of research appears either necessary or desirable for one or more of the purposes as set out in paragraph 3(2) of Schedule 2 to the 1990 Act or in paragraph 2(2)(a) of the Human Fertilisation and Embryology (Research Purposes) Regulations 2001. The Committee considered the stated aims of the project and the evaluation of the project by the three peer reviewers. The Committee noted that all three peer reviewers were of the opinion that the proposed research is necessary or desirable for the purpose of increasing knowledge about the development of embryos. Two of the peer reviewers additionally thought that the research was necessary or desirable for increasing knowledge about serious disease and enabling any such knowledge to be applied in developing treatments for serious disease.

The Committee agreed that in the context of the project of research these activities are necessary or desirable for the following purposes:

- Human Fertilisation and Embryology (Research Purposes) Regulations 2001: 2(2)(a) to increase knowledge about the development of embryos.
- Human Fertilisation and Embryology (Research Purposes) Regulations 2001: 2(2)(b) to increase knowledge about serious disease
- Human Fertilisation and Embryology (Research Purposes) Regulations 2001: 2(2)(c) to enable any such knowledge to be applied in developing treatments for serious disease.

The Committee based its decision on the fact that scientific understanding of the process of cell differentiation and of reprogramming is still at an early stage yet these processes are fundamental to our understanding of the optimal way of producing pluripotent cells and of then driving differentiation safely down specific routes. Until scientific knowledge in this area is more complete, the Committee believes that it is important for researchers to have the ability to use different model systems to obtain a fuller understanding of the molecular and cellular events involved. During the development of an embryo, cellular differentiation begins and the research proposed in this application provides new models to explore and learn more of this process. This research will also extend our knowledge of the above processes and hence, will in the longer term, inform our understanding of the molecular and cellular events involved in disease processes and inform the development of evidence based approaches to studies exploring potential novel therapies for diseases. The Committee were of the view that, increasing understanding in this area is an important step to increasing understanding about how diseases develop and opening up new avenues for

⁶⁷ [HFEA statement on its decision regarding hybrid embryos](#), 5 September 2007

treatment. For these reasons, the Committee was satisfied that the proposed research is, in fact, both necessary and desirable for the specified purposes.

12. The Committee agreed that they were satisfied that the proposed creation and use of human embryos was necessary for the purposes of this research. The Committee were satisfied that the proposed research could not be undertaken without the use of human embryos and was also satisfied that the proposed work justified the creation of human- animal cytoplasmic embryos, given the lack of available human oocytes. The Committee considered the emergence of new technologies for the reprogramming of adult somatic cells and agreed that, while very promising, these new technologies do not obviate the need for the basic research into differentiation of pluripotential embryonic stem cells as proposed in this application.⁶⁸

On April 2 2008 the creation of the UK's first part-human, part-animal was announced by Newcastle University where embryos using human cells and a cow egg had been made.

Previously, following the granting of licences for the research, a number of organisations had spoken out against the practice. Leading Catholics were quoted in the press and called for a free vote on amendments to prevent such research from taking place. The Catholic Herald reported:

Cardinal Cormac Murphy-O'Connor spoke out against the HFE Bill in a pastoral letter last month.

He said that MPs should ask for a vote of conscience and called for people to write to their MPs about the "profound questions of human life and dignity" that were raised by the Bill.

Addressing the Catholic laity of England and Wales in his capacity as president of the bishops' conference, he said: "Now is the time for our voices to be heard. This needs as many people as possible to write to - and better still - to go and see their MP and to register their deep concern about this Bill.

"Please urge your MP to support amendments to the Bill which would limit embryo research, recognise the need for children to have knowledge of their biological father, and which would reduce rather than increase the numbers of abortions.

"MPs should also request and be granted a free vote on those parts of this Bill which deal with fundamental issues of personal conscience."

Bishop Philip Tartaglia of Paisley made a similar appeal on behalf of the bishops of Scotland last week.⁶⁹

⁶⁸ HFEA, Research Licence Committee Meeting, [Minutes 28 November 2007 and 17 January 2008](#)

⁶⁹ ["Letter piles pressure on Brown to grant free vote"](#), *Catholic Herald*, 14 March 2008

b. *The Bill*

Clause 4 of the Bill will amend the HFE Act to ensure that the creation, storage and use of human animal hybrid embryos is regulated by the HFEA. In addition, the Bill sets out that such embryos can not be kept after either 14 days or the appearance of the primitive streak. This is in line with the current legislation for human embryos.

Schedule 2 to the HFE Act, as amended by paragraph 6 of Schedule 2 to the Bill, will continue to allow the mixing of sperm with the egg of an animal for the purposes of research into the normality or fertility of sperm.

c. *The 14 day rule*

The Warnock Report established 14 days as the time limit for keeping an embryo. It is at about this time the primitive streak develops, and after this time an embryo could not divide and become twins. The primitive streak represents the beginning of the first signs of neural development.

d. *Lords Amendments*

The term “inter-species embryos” used in the Bill as it entered the Lords was amended during the passage of the Bill to “human admixed embryos” throughout. This clarifies the type of research the Bill is hoping to regulate. As explained by Lord Darzi, the Under-Secretary of State, Department of Health, during Grand Committee:

A broad spectrum of entities can be created for research which contain both human and animal components. The Bill sets out a framework of regulation for those embryos defined in Clause 4 created using human and animal components where the resulting embryo in simple terms can be said to be towards the human end of that spectrum. That does not however cover the transgenic mice that are subject to Home Office regulation. It was suggested that an alternative term to “inter-species embryo” could be helpfully employed to make it clear that the Bill is not intended to apply to the whole spectrum of human, animal experimentation but only to those embryos that are predominantly human, resulting from modified human embryos or are the result of mixing human and animal gametes.

The term “human admixed embryos” has been suggested as a more accurate collective term to describe those entities, which the Bill seeks to bring clearly within the regulation of the Human Fertilisation and Embryology Authority. It was felt that the word “human” should be used to indicate that these entities are at the human end of the spectrum of this research. The term “mixed” was considered, but concerns were raised that such a term could be taken as referring only to those embryos that are a mixture of cells, such as chimera embryos, where the term also needed to include those embryos in which all the cells contain human and animal material but are genetically identical.

The term “admixed” is preferable as it does not lend itself to that sort of interpretation and is used in the chemical sciences to refer to a substance where two or more components are mixed in to each other. This term, developed in consultation with professional bodies such as the Academy of Medical Sciences, the Medical Research Council and the Wellcome Trust, allows for more focused debate on the research issues addressed in the Bill. This new term is more suitable by specifying that we mean human admixed embryos as opposed to

animal admixed embryos, the use of which remains more appropriately within the regulatory oversight of the Home Office.⁷⁰

Others, including Lord Alton of Liverpool, were more concerned that the terminology was being changed to provide a more publicly acceptable euphemism.⁷¹

A second amendment involves the powers to make regulations setting out how applications for licensed procedures should be determined. A Government amendment was accepted providing the Secretary of State with a regulation-making power to set out the evidence that may be required for such an application.

4. Ethics of embryo use

In the Warnock Report of 1985, the Committee wrote the following, enshrining the special status of the human embryo, in the laboratory as well as in life, as a fundamental principle.

11.17, page 63

Although, therefore, the law provides a measure of protection for the human embryo *in vivo* it is clear that the human embryo under our definition of the term (1.4) is not, under the present law in the UK, accorded the same status as a living child or adult, nor do we necessarily wish it to be accorded that status. Nevertheless we are agreed that the embryo of the human species ought to have a special status and that no one should undertake research on human embryos the purposes of which could be achieved by the use of animals or in some other way. The status of the embryo is a matter of fundamental principle which should be enshrined in legislation. **We recommend that the embryo of the human species should be afforded some protection in law.**

a. Status of the embryo

Arguments around research using embryos may be influenced by religious beliefs. This can lead to the “pro life” stance, which values the human life from conception as strongly as an adult. This viewpoint is consistent with viewing abortion as killing, and creation or destruction of embryos for scientific research as equally wrong. Any mixed tissue entity, that combines human genetic material with any animal material, should be viewed as a human because that human genetic material should be treated as an adult human, due to its inherent sanctity.

Biocentre, a bioethics think tank,⁷² describes some of the issues as follows:

The moral and legal status that should be afforded to mixed species entities is unclear. The blurring of this seminal boundary would threaten the principle of human equality and equal rights which are foundational in our culture and law.

⁷⁰ HL Deb, 15 Jan 2008 c1183

⁷¹ HL Deb, 15 Jan 2008 c1184

⁷² Biocentre webpage: [Human Animal Hybrids & Chimera](#) [on 2 May 2008]

The President's Council on Human Bioethics⁷³ accepted in 2004 that society should not be put into a position to judge the humanity or moral worth of ambiguous hybrid entities. Moreover critics are concerned that even if hybrid entities are destroyed early in their development, the mixing of human and animal embryos will further diminish the respect afforded to the human embryo.

Biocentre also mentions the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine⁷⁴

Article 13 – Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 18 – Research on embryos *in vitro*

Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

The creation of human embryos for research purposes is prohibited.

Those who object to the use of embryos are broadly in favour of the research going on into maximizing the potential of other sources of stem cells, such as umbilical cord and adult stem cells, as well as techniques that could convert normal cells into stem cells. Such cells could be used in treatments or research and the first successful experiments to reprogram human skin cells and induce pluripotency have been recently reported in journals this year.⁷⁵ While scientists continue to argue that there is a need for basic human embryo research to complement this reprogramming research, other organisations believe such research is becoming unnecessary. The Christian Medical Fellowship released the following Statement as the Bill completed its passage in the Lords:

Christian Medical Fellowship fully supports science but insists it must operate within ethical boundaries. The HFE Bill transgresses these.

Animal-human hybrid embryos are unnecessary because reprogrammed adult skin cells have all the potential of human embryonic stem cells, and unethical because their creation would blur boundaries between humans and animals and undermine human dignity.

It is wrong to use IVF to create children as a means to an end for others – 'saviour siblings'. It is wrong deliberately to create children without fathers. Medical and sociological evidence shows that children need fathers, as recognised elsewhere in public policy.

⁷³ [The President's Council on Human Bioethics](#) website – the Council advises the U.S. President on ethical issues related to advances in biomedical science and technology

⁷⁴ [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine](#) Oviedo, 4.IV.1997

⁷⁵ [More induced pluripotency](#), *Nature*, 28 February 2008

Amendments to liberalise abortion law should be opposed. 200,000 abortions a year is too many. CMF supports appropriate restrictions – reducing the upper gestational limit, ending discriminatory abortion for disability, and requiring a ‘charter for informed consent’.⁷⁶

Further information on the views of interested groups is contained in Appendix 3.

5. Issues of consent

a. The Bill

Under the HFE Act consent is required before a person's gametes can be used to create an embryo. There are no exceptions to the consent requirements.

The Bill updates the HFE Act to take account of the fact that an embryo can now be created using not only gametes but also through SCNT using human cells, or another embryo or human admixed embryo. The Bill amends Schedule 3 to the HFE Act to require an "effective consent" from a person whose cells (or gametes) are used to create an embryo or human admixed embryo. In addition, consent will be required if that embryo is used to create another embryo.

The Bill also amends the *Human Tissue Act 2004* to ensure consent must be obtained under these new provisions for the use of human cells to create or alter an embryo or human admixed embryo.

b. Debate

A number of scientists and scientific organisations, including the Academy of Medical Sciences, Medical Research Council, Royal Society and Wellcome Trust, have called for the requirement of consent to be waived under certain circumstances.

Medical research establishments have built up repositories of cells often from patients with specific rare conditions. These are of particular importance because new therapeutic cloning techniques mean that embryos can be created from these cells that also carry the genetic condition of the patient from which they were taken. Research on these embryos could provide useful information on the origins, development and treatment of these diseases. However, to create such an embryo would require the consent of the donor and this may not always be possible.

These concerns were expressed in a letter printed in the Times signed by leading scientists in the field:

Sir, Both Gordon Brown and Tony Blair have called for the UK to be a world leader in stem cell science, aimed at increasing knowledge about the causes and potential treatment of serious, incurable degenerative conditions, including Parkinson's disease, diabetes and motor neurone disease. This Government has

⁷⁶ Statement from the Christian Medical Fellowship for the House of Commons' Library Research Paper on the HFE Bill, February 2008

a good record in ensuring that such research is permitted in this country, but strictly regulated by the Human Fertilisation and Embryology Authority. The new Human Fertilisation and Embryology Bill, currently going through Parliament, is generally progressive in its proposals for regulating the production of embryos, up to only 14 days-development, in the laboratory. However, we, as stem cell scientists and supporters of biomedical research, are very concerned about the proposed ban on the generation of embryos in such research by the use of cells for which the donors did not, or could not, give specific consent.

We fully agree that in the future such consent should be a requirement and that it would be wrong to use previously donated cells if there were good reason to believe that the donor would have specifically objected to their use in embryonic stem cell research. However, many existing cell and tissue samples and cell lines were donated, for any research purpose, by patients (now untraceable) with particular diseases, before this sort of research was even imagined. These cells have been well characterised over many years, or have unique properties and may therefore be the best samples to use for the derivation of embryonic stem cells. Such stem cell lines would be of great value in understanding how diseases develop, as well in the search for therapies.

Lord Patel, the Chairman of the UK Stem Cell Network Steering Committee, is today seeking to amend the bill in the House of Lords to allow the use of existing, lawfully obtained, anonymised cells or cell lines, with untraceable donors, where the HFEA agrees that they are more scientifically suitable than alternative sources.

We are alarmed that the Government has expressed opposition to this amendment, even though it mirrors a similar provision in the Human Tissue Act 2004, regarding anonymous untraceable "existing holdings".

We urge the Government to accept this important improvement to the Bill, which will help to maintain the UK's reputation as the place of choice for this exciting and world-leading medical research.⁷⁷

In response to Lord Patel's amendment and a number of others, which were not accepted, the Parliamentary Under Secretary of State for Health, Lord Darzi, wrote to Peers. The letter set out the Government's position and a consideration of the European Convention on Human Rights.

- The use of human cells to create embryos or human admixed embryos engages Article 8 (right to private and family life). Private life is a broad term that encompasses the right to personal autonomy. This is likely to include a person's right to determine under what circumstances their genetic material is used to create an embryo or human admixed embryo
- The use of a person's genetic material, without their express consent, to create embryos and their subsequent use and storage would interfere with a person's rights under Article 8 of the Convention

⁷⁷ Stem cell research is vital and can save lives; Letter, *Times*, 21 January 2008.

- An interference with Article 8 needs to be justified and must be proportionate. In principle, a justification for using cell lines without the consent of the person to whom they relate could be scientific need. However, on the evidence provided to the Government prior to Report stage, it had not been demonstrated that there was such a need because it appeared to be possible to use cells where consent is in place. Although not using existing cell lines might create extra administrative burdens, this would not be sufficient justification to meet the requirements of Article 8
- The debates on this issue at Report stage and further discussions with scientific researchers have more clearly identified the scientific need to use existing cell lines. A compelling case has been made that the requirement for express consent could, in certain circumstances, impose a significant burden on research in this field. On this basis the Government takes the view that **it would be possible to make an exception to the requirement for express consent, provided that stringent safeguards are in place. We would expect that such an exception would focus on situations where the inability to continue using existing cells would have significant adverse effects on research, where such research would be in the public interest.** The detail of such safeguards to ensure compliance with Article 8 requires further consideration.⁷⁸

Lord Patel tabled amendments to provide a parental consent on behalf of their children to use cells lawfully taken from them to create embryos through SCNT. Such embryos could be used to research serious disease or serious medical conditions.⁷⁹

Baroness Royall of Blaisdon responded for the Government at Report Stage:

The Bill sets out to ensure that human and human-admixed embryos may only be created for research purposes, and only where the person to whom the cells belong gives their explicit consent. These requirements have been introduced to reflect the special status of the embryo. No one can give consent on behalf of an adult who lacks capacity, and, for the same reasons, I do not believe that a child's cells should be used to create embryos or human-admixed embryos without that child's own consent.

If a child is incapable of giving consent to the creation of an human or human-admixed embryo themselves, because they are too young to do so, it would be wrong for any person, including the parents, to make that decision for them, given the significance of creating an embryo using their genetic material.

I have heard the powerful statements from the noble Lords, Lord Patel and Lord Walton of Detchant, but the Government take the view that we should not, in any circumstances, presume that a person's cells can be used in the creation of

⁷⁸ Department for Health, [Letter from Lord Darzi of Denham to All Peers who spoke during debate on the Human Fertilisation and Embryology Bill](#), 31 January 2008

⁷⁹ [HL Deb, 21 January 2008 c50](#)

embryos without their consent or knowledge. I therefore invite the noble Lord to withdraw his amendment.⁸⁰

The amendment was withdrawn.

E. A National Bioethics Commission

1. Background and the Joint Committee on the Human Tissue and Embryos (Draft) Bill

Unlike in the United States and many other European countries, the UK does not have a national bioethics commission or committee to advise and take decisions on bioethical issues in scientific research. The Joint Committee on the draft Bill summarised how the current ethical framework operates within the HFEA and the HTA:

Shirley Harrison, Chair of the HFEA and the HTA, told us that both organisations “obviously deal with major ethical issues all the time and the HFEA has an Ethics and Law Group which is advisory to it and that looks at any specific ethical issues”. In the HTA ethical issues were “a strand within all of the licensing codes”. (Q 168) The HFEA also has a “horizon scanning panel ... which meets two or three times a year and looks at potential future issues that might be coming up in science.” (Q 182) To gain a wider ethical input, the HFEA often supplements its Ethics and Law Group with additional expertise. Angela McNab, Chief Executive of the HFEA, told us that the HFEA Ethics Committee often “draw[s] in through co-opting a range of wider experience than we would be able to draw just from Authority members ... What it does is it gives us a deeper or richer texture to the discussions and debates that take place in the Ethics Committee ... I think the model we have works very well”. (Q 169)⁸¹

Also supporting bioethics in the UK are Local and Multi-centre Research Ethics Committees (LRECs and MRECs). They are overseen by the Central Office for Research Ethics Committees (COREC). The committees consider the ethics of proposed research projects which will involve human subjects, and which will take place broadly within the NHS. The role of COREC is to maintain an overview of the operation of the research ethics system in England, and alert the Department of Health and other responsible authorities if the need arises for them to review policy and operational guidance relating to Research Ethics Committees.⁸²

In addition to this, the Nuffield Council on Bioethics examines ethical issues raised by new developments in biology and medicine. It was established by the Nuffield Foundation in 1991 and is an independent body, funded jointly by the Foundation, the Medical Research Council and the Wellcome Trust. Membership of the Council includes

⁸⁰ [HL Deb, 21 January 2008 c52](#)

⁸¹ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p19

⁸² Science and Technology Committee, [Human Reproductive Technologies and the Law](#), fifth report session 2004-05, HC 7-I, 24 March 2005, p146

clinicians, lawyers, philosophers, scientists and theologians.⁸³ The Council's terms of reference require it:

1. To identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;
2. To make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;
3. In the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.⁸⁴

The Joint Committee on the Human Tissue and Embryos (Draft) Bill looked at the issue of bioethics regulation in the UK and examined: whether what we have is still an appropriate model; whether it is appropriate for ethical decisions to be taken by the regulator (currently the HFEA); or whether ethical decisions should be taken by an outside body.⁸⁵ Some witnesses told the Joint Committee that the current ethical framework, as provided by the HFE Act, was still “an appropriate model”.⁸⁶ Others said that medicine and science had moved on and that because of this the HFE Act has “developed fundamental flaws [that] have become apparent and need to be addressed.”⁸⁷ The Joint Committee summarised some of the arguments against the current system: these included a lack of breadth of ethical representation within the HFEA and concerns about the HFEA’s “dual role in inspection and thinking about really deep issues of bioethics”.⁸⁸

The Joint Committee received evidence both about how to build an ethical input into the then proposed new regulator, RATE, and also about how to establish an ethical input outside the regulator. In terms of ethics within the regulatory framework, the Joint Committee received a number of suggestions as to how this might work best. Several witnesses suggested to the Joint Committee that RATE should establish a separate ethics committee or similar. The UK National Stem Cell Network suggested to them that the ethical framework “must be engineered by RATE, which should use its powers to set up appropriate sub-committees comprised of expert individuals who are not necessarily part of the Authority’s existing infrastructure”.⁸⁹ Officials from the Department of Health told the Joint Committee that it would be the RATE board “who would look at that advice

⁸³ [Nuffield Council on Bioethics](#) website [on 2 May 2008]

⁸⁴ Nuffield Council on Bioethics, [Terms of Reference](#) [on 2 May 2008]

⁸⁵ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, chapter 4

⁸⁶ Hugh Whittall, Director, Nuffield Council on Bioethics, Joint Committee on the Human Tissue and Embryos (Draft) Bill, Evidence, 1 August 2007, HL 169-II/HC 630-II 2006-07, Q5

⁸⁷ Professor Alison Murdoch, Professor of Reproductive Medicine at Newcastle Fertility Centre, Joint Committee on the Human Tissue and Embryos (Draft) Bill, Evidence, 1 August 2007, HL 169-II/HC 630-II 2006-07, Q275

⁸⁸ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p19

⁸⁹ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p19

and take decisions, partly from a wider perspective in terms of social and legalistic perspectives.”⁹⁰ The Joint Committee pointed to a general “desire for a wider breadth of representation, in response to criticism of the current system”.⁹¹ A perceived lack of representation of some viewpoints appeared to be the main criticism against keeping the ethical framework within the regulator:

The Church of England Mission and Public Affairs Council favoured “an Ethics Committee, working closely with but not controlled by the HFEA/RATE, on which a broad range of views were represented” and said the constitution of this committee “should include representatives of those who cannot serve on HFEA/RATE because of their clear opposition to embryo research. We feel that such viewpoints should not be marginalised or ignored”⁹²

The Joint Committee also heard evidence that ethical input should come from outside the regulator, and in particular on whether a National Bioethics Commission should be established. The arguments for this were summarised:

Lord Brennan strongly supported a National Bioethics Council created on a statutory basis, with a diverse membership, supported by public money and separate from government and agencies. (Ev73) Several organisations also supported a national ethics committee, either to meet a gap in the draft Bill, or to overcome the inherent conflict of a regulator funded through licence fees also being required to ensure a broad range of ethical perspectives. Professor Gillon told us “I think [a National Bioethics Committee] is a good idea myself but there are plenty of arguments against it” and noted that the Nuffield Council on Bioethics acted as a de facto National Bioethics Committee. (Q 805) The Medical Ethics Alliance thought it would have been helpful if a specific committee had been set up to consider ethical matters either before or in parallel with this consultation (Ev13)⁹³

The Joint Committee reported that the main opposition against the establishment of a bioethics commission came from the Department of Health. Officials from the Department of Health told the Joint Committee that the Human Genetics Commission, advisory groups to the HFEA and the Parliamentary Science and Technology Committee all provide a great deal of “advice”, “questions” and “inform debate” and that they were “not aware of an international bioethics commission that works in any better way.”⁹⁴

In concluding on this matter, the Joint Committee expressed concern that the draft Bill lacked the explicit underpinning ethical framework which in 1990 was provided by the Warnock Report. It said that whilst it accepted that the Warnock Report still provided a partial ethical framework, that it agreed with those who argue that scientific

⁹⁰ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p19

⁹¹ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p19

⁹² Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p20

⁹³ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p20

⁹⁴ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p20

developments have made ethical decisions more difficult.⁹⁵ The Joint Committee recommended that it should be for Parliament to set the ethical framework and recommended that there should be a Parliamentary bioethics committee:

We are unable to support proposals for a national bioethics committee. Ultimately it must be for Parliament to set the ethical framework, taking the widest range of advice. We consider that an ethical input should be found from within Parliament and we recommend that Parliament should establish a joint bioethics committee of both Houses to provide ethical input to legislation raising significant issues in bioethics, such as the current draft Bill.⁹⁶

a. *Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill*

The Government published its response to the Joint Committee's report on 8 October 2007.⁹⁷ The Government agreed with the Joint Committee on the value of receiving ethical input from Parliament but again stated that it was against a national bioethics body:

The Government shares the Committee's view of the value of debating bioethical issues, and the benefit of addressing complex issues in Parliament. We note that the Committee recognise that they are 'unable to support proposals for a national bioethics committee'. The Government shares this view. However, it would ultimately be a choice for Parliament as to whether to establish a joint bioethics committee of both Houses.⁹⁸

2. Lords Debate

At the Second Reading debate of the Bill in the Lords, there was a general consensus in support of a Parliamentary bioethics committee.⁹⁹ Lord Brennan argued in addition for a national bioethics commission to be established saying that it would be necessary for "democracy":

Lord Brennan: My Lords, I propose for the consideration of the House now and in Committee the creation of a national bioethics commission in this country. The great physicist Niels Bohr said that it was dangerous to make predictions, especially about the future. He was right about his own scientific world. We are now at a stage where the speed of scientific advance is very fast indeed. It is outstripping the capacity of our people to understand what is happening. It thereby impairs our ability to set an ethical framework in which those advances should be made. That is not an acceptable state of affairs in a democracy. Science must speak and explain to us what it is doing and where it might go. We

⁹⁵ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p21

⁹⁶ Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report, 1 August 2007, HL 169-I/HC 630-I 2006-07, p21-22

⁹⁷ Department of Health, *Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill*, Cm 7209, 8 October 2007

⁹⁸ Department of Health, *Government Response to the Report from the Joint Committee on the Human Tissue and Embryos (Draft) Bill*, Cm 7209, 8 October 2007 p4

⁹⁹ HL Deb 19 November 2007 c663 and HL Deb 21 November 2007 c836

are entitled to what I would call scientific social responsibility. With it we, the people, can understand better, be more aware and therefore be able to participate in the democratic processes about life sciences which so fundamentally affect us.

Regulatory control is plainly necessary in this area, but it is not enough. Control may give people confidence, but an ethical framework will give them trust. We should seek to establish a combination of the two under the bioethical reforms. We [do] not need only confidence and trust, but some basic understanding about probability—the “mights” of life as against the “woulds”, “wills” and “surelys”. Very few people ever think about probability when examining the world in which they live. It is very important in this context. Do they think about risk in this context? Hardly at all. They need educating. We need educating. Therefore, it is appropriate, is it not, to consider a national bioethics commission? While I agree with much of what my noble friend Lord Winston says, I simply do not agree that we already know what most people think about these issues. We, educated people, ask for evidence about the public’s feelings on things, but without any proper understanding and awareness, how can they give us evidence? We have a state in which one almost patronises them.

What of the commission? Its function was proposed over 25 years ago by Sir Ian Kennedy, certainly not on any religious basis, but entirely because of the ethical framework in which science was then moving. Such commissions exist in Australia, Denmark, Germany, France and other countries, and they work. The societies there benefit from those commissions. They do not determine or decide—they inform; they make one aware; one understands better and one plays one’s democratic part more productively.

[...]

If we do not have such a body we are left with some government regulators with ethical committees, an unaccountable private body and the Government. In Great Britain in 2007—this new age of science—that is not enough.

What would this body therefore do? It would be set up by statute with a wide bioethics remit; it could function at reasonable cost; it would be independent; and it would be continuous. I know of no country where the participation of different views in any way detracts from the effectiveness of these commissions on the countries in which they operate. What are the benefits for us? It closes a democratic gap; it enables science to be responsive to it and thereby responsible to us; it benefits the Government; and it benefits Parliament because it compliments rather than subtracts.

The Joint Committee was reluctant to accept it. Using its phrase, I could detect “no sound point of principle” why it was reluctant, unless it thought that the recommendation was designed to avoid parliamentary decision making. Far from it; it is to add to it as the basic democratic requirement. When we talk about these things in a democracy, it is not just the letter of the law; it is a culture of democracy that involves us all.¹⁰⁰

In his concluding remarks the Parliamentary Under-Secretary of State, Department of Health, Lord Darzi of Denham, restated the Government’s position that the present

¹⁰⁰ HL Deb 19 November 2007 c727

system of a number of bodies considering and advising on ethical issues is preferable to establishing a national bioethics committee. He said that whether to establish a standing committee on bioethics of both Houses, or whether to leave the current system in place, would be a matter for Parliament to decide:

Many speakers have talked about how bioethical issues are considered and debated. The noble Lord, Lord Brennan, spoke powerfully in favour of an independent bioethics commission. The noble Baronesses, Lady Neuberger and Lady Hooper, among others, raised the idea of a parliamentary standing committee to consider these issues. The Government have considered the idea of an independent commission on several occasions and have expressed their view that the present system, whereby a number of bodies are able to consider and advise on various ethical issues, is preferable. The Joint Committee that scrutinised the Bill also found that it could not support the idea of a bioethics commission. However, the Government share its view on the value of debating bioethical issues and the benefits of addressing complex issues in Parliament. As I hope noble Lords will appreciate, however, whether to establish a standing bioethics committee of both Houses, or whether the current structure is preferable, is ultimately a matter for Parliament itself.¹⁰¹

a. Lords Committee Stage

An amendment moved by Lord Alton of Liverpool at Committee Stage in the Lords to introduce a new clause into the Bill to establish a National Human Bioethics Commission prompted a lengthy debate on its pros and cons. Lord Alton moved Amendment No. 66:

After Clause 32, insert the following new Clause—

“National Human Bioethics Commission

(1) There is to be a body corporate called the National Human Bioethics Commission.

(2) Schedule (National Human Bioethics Commission) has effect.”¹⁰²

In his speech, he set out how he envisaged the commission might operate and be managed and said that it could be complementary to any Parliamentary Committee that might be established:

Such a committee would have the authority and standing of an independent statutory body. Its membership should encompass relevant professional expertise, patients and other user-group interests, as well as major religious and ethical groupings. Membership must reflect the diversity of positions within society, and appointment procedures must be public and transparent. Although independent, such a committee would be responsible to Parliament through a Minister to whom it should deliver an annual report, including recommendations for policy and such additional reports as may be commissioned or submitted. I know that the noble Baroness, Lady Williams of Crosby, has canvassed the idea,

¹⁰¹ HL Deb 21 November 2007 c865

¹⁰² HL Deb 12 December 2007 c259

to which I hope she will refer during the proceedings in Committee, that this body will also monitor legislation and be able to evaluate its effectiveness. Its remit would be the entire range of bioethical issues, including, but not confined to those concerning reproduction.

Amendments Nos. 66 and 67 seek to establish such a body. Some have argued for a new in-house Westminster committee. It is open to the authorities in both Houses to produce a body if they feel that that would enhance the work of the existing Select Committees. Those two ideas are not mutually exclusive; indeed, they could complement one another very well.¹⁰³

In the debate, Baroness Deech argued against the establishment of a national bioethics commission. She argued that we already had enough bodies which advise on ethical matters. She also said that in other countries, such commissions have been found to be not very influential, not very forward-looking and not very representative of different viewpoints:

Baroness Deech: The idea put before us is a good one in principle but I think it has been oversold for three reasons. We already have the Human Genetics Commission, we have the Nuffield Council on Bioethics, we have reports from the Wellcome Institute and we had excellent reports from all our professional and learned societies.

[...]

In my experience, the further south and east you go in Europe, the more these committees are dominated by religious people—not that there is anything bad in that, but they can be used to hold back the progress of the law. In the USA, the bioethics commission, it has been alleged, is filled with people who support the President's view, whoever is the president of the day. Its reports have regularly been ignored and they have been forward-looking. Parliament is ultimately the ethical regulator. This is a country governed by law and that takes me to my final argument, which is that not much can be achieved by a bioethics commission.¹⁰⁴

Through practical examples of her own experience chairing the HFEA, she said that ethical decisions often had to be taken quickly, often at the last minute and on a Friday afternoon. She suggested that it was more important to have good laws and a solid legal framework that could be drawn on to make an ethical decision, rather than referring a decision to a commission which might ultimately take too long to make any decision that might make a difference.¹⁰⁵

At the end of the debate on the amendment, Lord Alton withdrew the amendment to allow for further discussion on the issue at Report Stage.¹⁰⁶

¹⁰³ HL Deb 12 December 2007 cc260-261

¹⁰⁴ HL Deb 12 December 2007 c261-262

¹⁰⁵ HL Deb 12 December 2007 c262

¹⁰⁶ HL Deb 12 December 2007 c283

b. Lords Report Stage

At Report Stage in the House of Lords, Baroness Williams of Crosby moved an amendment which would have the effect of establishing a national bioethics commission:

After Clause 56, insert the following new Clause—

“National Human Bioethics Commission

(1) There is to be a body corporate called the National Human Bioethics Commission.

(2) Schedule (National Human Bioethics Commission) has effect.”¹⁰⁷

In her speech, she explained how she thought that a national bioethics commission would work and who would be a part of it:

First, such a commission would be appointed by the Secretary of State. Secondly, it would cover a wide range of relevant occupations—medical practitioners, research scientists, philosophers, ethicists and others who are concerned with science and the way in which science should be assisted and encouraged to be understood by a much wider public. Its functions would include monitoring scientific advances in bioethics, considering the ethical issues that arise and looking at the consequences of legislation passed by Parliament—I stress this—in the light of subsequent evidence.¹⁰⁸

She also stated that a Parliamentary select committee on bioethics would be a good idea, but should not be seen as an alternative to a national bioethics commission. She explained that decisions in Parliament were not always taken according to conscience, but often according to the whip:

[...] there are two kinds of vote in Parliament. One is a free vote, where people decide, on the basis of what they have heard and after discussion, what they think the proper judgment ought to be. The other kind is a whipped Vote.

[...] A Government also have a right to push for Bills that they believe in. The Government have a right to press for this country to be the leading place in which human biology is conducted. There are arguments for that. However, we are entitled to ask, sometimes, what those motives might be.¹⁰⁹

In concluding the debate, Baroness Williams begged leave to withdraw the amendment, explaining that:

I do not want to detain the House any longer and propose to withdraw the amendment, but I hope that the attention of another place, as the noble Lord, Lord Elton, said, can be drawn to this debate and that it will be taken into account in another place. While at the moment to press this to a Division would be

¹⁰⁷ HL Deb 28 January 2008 c479

¹⁰⁸ HL Deb 28 January c479

¹⁰⁹ HL Deb 28 January c483

inappropriate, I feel passionately that to abandon this at this moment because there is not going to be a Division could lead us to pass up a huge and essential opportunity to create a machinery and mechanism of oversight that does not exist at present and without which we shall rue the day that we failed to take this opportunity. I beg leave to withdraw the amendment.¹¹⁰

The amendment was withdrawn.

F. Issues of paternity and parenthood

One of the issues the draft Bill confronts is the definition of parent. Increasing use of artificial reproductive technologies means that there is a greater spectrum of parenthood, ranging from genetic parents giving birth to their own children, through parents giving birth to non genetic offspring who were conceived with sperm and egg donations, to same sex couples being the parents of a offspring born to a surrogate. The distinction between biological and nurturing parenthood raises the issue of who is named as parent on a birth certificate.

1. Need for a father

Section 13 of the HFE Act mandates a doctor to consider the welfare of any child that may be created by IVF. Section 13(5) of the Act states that:

A woman shall not be provided with treatment services unless account has been taken of the welfare of the child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.

In addition the HFEA is required by section 25(2) of the HFE Act to provide guidance on how this duty should be carried out. This is contained in the HFEA's Code of Practice to licence holders which currently states:

Where the child will have no legal father, the treatment centre should assess the prospective mother's ability to meet the child's/children's needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.¹¹¹

HFEA data suggests that of a total of 40,484 IVF treatment cycles in 2006, 1.4 percent were to registered single females and 0.5 percent to registered lesbians. Of the 3,864 Donor Insemination treatment cycles, 18 percent were to registered single females and 21.1 percent to registered lesbians.¹¹²

In March 2005 the House of Commons Science and Technology Committee, in its report on *Human Reproductive Technologies and the Law*, recommended that section 13(5) should be altered in its current form, on the basis that it discriminated against people with

¹¹⁰ HL Deb 28 January c501

¹¹¹ HFEA, [Code of Practice](#), 30 November 2007

¹¹² HFEA, [A long term analysis of the HFEA Register data: 1991-2006](#), July 2007.

fertility problems, was impossible to implement, and is of questionable practical value. The report was acknowledged by the Government, which stated in its White Paper of 2006, that it was not convinced of the need for this part of the HFE Act to prevent harm;

[...] particularly when weighed against the potential harms arising from the consequences of encouraging some women who wish to conceive to make private arrangements for insemination rather than use licensed treatment services.¹¹³

The resulting *Human Tissue and Embryos (Draft) Bill* would have simply removed the text "(including the need of that child for a father)", from the HFE Act. But when the matter was raised by the Joint Committee in their scrutiny of the draft Bill they recommended that clause was retained in some form and that its alteration was put to a free vote.

243. We recommend that the proposal to remove the 'need for a father' provision from section 13(5) of the 1990 Act should be put to a free vote of both Houses of Parliament. To inform that vote, the balance of view of this Committee is that it would be detrimental to remove entirely the requirement to take into account the 'need for a father'. Instead, we recommend that the current provision in section 13(5) on "(including the need of that child for a father)" should be retained but in an amended form in a way that makes clear it is capable of being interpreted as the 'need for a second parent' in line with the parenthood provisions currently in Part 3 of the draft Bill. In making this recommendation, we do not seek to discriminate against single women seeking treatment and we recommend that in such circumstances and the requirement to consider the need of a child for a second parent should, as now, not be a barrier to treatment.

In the Government's response to the Joint Committee Report, they explained why they would not be changing the wording of the draft Bill.

The Government carefully considered whether research evidence supported the continued reference in primary legislation to a duty on clinicians to give specific attention to the need for a father. DH's consultation document summarised the findings of research in this area, which tend to show that the factor of prime importance is quality of parenting rather than parental gender per se.

On balance, the Government decided to remove the reference to the need for a father but to retain in primary legislation a general duty to take account of the welfare of the child. In doing so, the Government also took account of the House of Commons Science and Technology Committee's view, in its 2005 report, that: *The requirement to consider whether a child born as a result of assisted reproduction needs a father is too open to interpretation and unjustifiably offensive to many. It is wrong to imply that unjustified discrimination against 'unconventional families' is acceptable.*

The Government believes that amending the reference to the need for a father to refer instead to a 'second parent' (while also ensuring that this does not impose a barrier to single women receiving treatment) would not add significantly to the

¹¹³ [Review of the Human Fertilisation and Embryology Act](#): December 2006. Cm 6989.

Government's proposal to retain a mandatory licence condition requiring that the welfare of the child be taken into account before providing treatment.

As noted in response to recommendation 13 above, the issue of free votes is ultimately a matter for the Government and the opposition parties to decide upon at the appropriate time

a. *The Bill and Debate*

As introduced, clause 14(2) of the Bill would omit from Section 13(5) of the HFE Act "(including the need of that child for a father)". This was amended by the Government during Report Stage. Now clause 14(2)(b) of the Bill amends the reference to a child's need for a father so that the licence condition to be imposed under section 13(5) of the HFE Act would refer instead to the child's need for "supportive parenting". In addition clause 23 makes the same amendment to section 25(2) which concerns the guidance to be given about that licence condition. Section 13(5) of the HFE Act as amended would therefore require licence holders to consider the welfare of a child who may be born as a result of the treatment, including the need of that child for supportive parenting, and the welfare of any other child who may be affected by the birth. Furthermore this will continue to be a matter on which the HFEA must provide guidance.

During the Report Stage debate Lord Darzi explained that the Government had opted for this new wording following comment at Committee Stage, when it had become clear that there was concern over dropping the term "including the need of that child for a father" and devaluing the role of a father. The term "supportive parenting" was chosen to maintain the value of a father while not impeding same sex couples from seeking fertility treatment.¹¹⁴

This remains a contentious clause that has attracted interest from lobbying groups calling for its removal, along with the proposed changes to birth certificates,¹¹⁵ as an attack on fatherhood in general. The Christian Medical Fellowship (CMF) has campaigned on this issue.

Removing the requirement to consider the need for a father for children created by IVF will further damage families and society. Research shows that children with fathers, in stable families, are healthier, happier, and do better in education and employment. CMF upholds the God-given ideal for families. No-one has an absolute right to have a child of their choosing, in their way, at their time, and for their own purposes.¹¹⁶

Equally organisations calling for equal rights for same sex couples have welcomed the progress of the Bill.

The House of Lords previously rejected an amendment to the Human Fertilisation and Embryology Bill which would have had a negative impact on lesbian couples and single women seeking assisted fertility treatment at

¹¹⁴ [HL Deb 21 January 2008 c54](#)

¹¹⁵ See following section on Registration of births in England and Wales.

¹¹⁶ Christian Medical Fellowship webpage: [HFE Bill](#) [on 2 May 2008]

fertility clinics. Peers voted against it by 164 votes to 93 during Report stage debate on 21 January.

At present, clinics have to consider the role of a father before granting treatment. Peers approved a Government amendment to replace the current 'need for a father' requirement with a requirement to consider the need for 'supportive parenting'. Stonewall welcomes this step - the current system routinely encourages women to make informal arrangements outside the protection of formal healthcare.

There is no credible evidence to support the suggestion that children of lesbian parents are at any disadvantage developmentally compared to others.¹¹⁷

2. Registration of births in England and Wales

The *Births and Deaths Registration Act 1953* (as amended) (*BDRA 1953*) includes the provisions for the registration of births in England and Wales. The Act consolidated the provisions of previous Acts dating back to 1836. The 2003 consultation paper *Civil registration: delivering vital change* set out information about the details recorded in the birth register.¹¹⁸ These requirements are available on the General Register Office website.¹¹⁹

a. The Joint Committee on the Human Tissue and Embryos (Draft) Bill

The Joint Committee's report, published on 1 August 2007, observed that Part 3 of the draft Bill "seeks to take a new approach to parenthood, moving towards the concept of parenthood as a legal responsibility rather than a biological relationship".¹²⁰ The report noted that a "significant amount" of the evidence on the merits of this approach was "quite divided", although "[m]any witnesses gave general support to the Government's approach towards legal parenthood".¹²¹

The Committee considered the question of whether donor-conception should be noted on an individual's birth certificate:

We recognise the force of the argument that the fact of donor conception should be registered on a person's birth certificate. This would create the incentive for the parent(s) to tell the child of the fact of his or her donor conception and would go some way to address the value of knowledge of genetic history for medical purposes. Moreover, unlike where children are born through natural conception, assisted conception by its nature involves the authorities and we are deeply concerned about the idea that the authorities may be colluding in a deception. However, we also recognise that this is a complicated area involving the important issue of privacy, as well as issues of human rights and data protection.

¹¹⁷ Stonewall webpage: [Fertility Review](#) [on 2 May 2008]

¹¹⁸ *Civil registration: delivering vital change*, HMSO, 2003, pp6-10

¹¹⁹ General Register Office webpage: [Births](#) [on 2 May 2008]

¹²⁰ Joint Committee on the Human Tissue and Embryos (Draft) Bill, [Human Tissue and Embryos \(Draft\) Bill Report](#), 1 August 2007 HL 169-I/HC630-1 2006-07, p70

¹²¹ *ibid*, p70

We therefore recommend that, as a matter of urgency, the Government should give this matter further consideration.¹²²

A large amount of evidence was submitted to the Joint Committee, which has been published in a separate volume to the report.¹²³

The Government published its response to the Joint Committee's report in October 2007.¹²⁴ On the issue of recording donor conception on a person's birth certificate, the Government replied:

The idea of including 'by donation' on donor-conceived children's birth certificates is a matter that has been raised in the past. The Warnock Committee stated: 'We are of the view that consideration should be given as a matter of urgency to making it possible for the parents in registering the birth to add "by donation" after the man's name.'¹²⁵ The Government's position to date is that it is preferable that parents are educated about the benefits of telling children that they were donor-conceived rather than forcing the issue through the annotation of birth certificates.

70. However, this is a sensitive area and the Government recognises the Committee's concern, as well as the importance of allowing donor-conceived people access to information about their genetic background. We believe that the issues need to be considered carefully, including constructive dialogue with stakeholders, and we will keep the matter under review.¹²⁶

b. The Bill

Part 2 of the Bill concerns the determination of legal parenthood in future cases involving assisted reproduction. According to the Explanatory Notes, it "introduces a new concept of parenthood for a mother's female partner in certain circumstances, making equivalent provision to that for opposite sex couples".¹²⁷ The Bill would amend the *BDRA 1953*, as well as the *Registration of Births, Deaths and Marriages (Special Provisions) Act 1957*. The provisions concerning the registration of births and legal parenthood are unchanged from those included in the draft Bill.

The Bill's provisions include the following:

Meaning of mother and father

Clause 33 provides that the meaning of "mother" would remain the same as in the *Human Fertilisation and Embryology Act 1990* (HFE Act): the woman who carries a child after assisted reproduction anywhere in the world is the child's mother, unless the child is adopted or parenthood transferred through a parental order.

¹²² *ibid*, p73

¹²³ Joint Committee on the Human Tissue and Embryos (Draft) Bill, [Human Tissue and Embryos \(Draft\) Bill Report](#), 1 August 2007 HL 169-II/HC630-II 2006-07

¹²⁴ [Government Response to the Report from the Joint Committee on the Human Tissue and Embryos \(Draft\) Bill](#) Cm 7209, October 2007,

¹²⁵ Cm 9314, *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, July 1984, paragraph 4.25

¹²⁶ Cm 7209, p19

¹²⁷ *ibid*, p3

Clause 35 provides that the husband of a woman who conceived a child as a result of treatment with donor sperm would continue to be treated as the child's father, unless it was shown that he did not consent to his wife's treatment.

Unmarried heterosexual couples

Under provisions in the HFE Act, an unmarried man may be considered to be the father of a donor-conceived child if he is 'treated together' with the mother in a licensed clinic. Clauses 36 and 37 of the Bill would replace these provisions.

Clause 36 sets out the circumstances in which an unmarried man could be treated as the father of a child where the agreed "fatherhood conditions" apply.

Clause 37 sets out the "fatherhood conditions" that would apply in relation to treatment provided to a woman under a licence: for a man to be the father, the couple must each have given notice of consent to him being treated as the father; neither must have given notice withdrawing their consent; and the woman must not have given notice of consent to anyone else being treated as the child's parent.

Same sex partners

The *Civil Partnership Act 2004* created a new legal relationship, which can be registered by two people of the same sex, and which gives them the ability to obtain legal recognition for their relationship.¹²⁸ Information on civil partnerships is available from the Women and Equality Unit website.¹²⁹

Clause 42 would provide that where a female civil partner gives birth to a child conceived following assisted reproduction then she is the mother of the child and her civil partner is the other parent, unless she did not consent to the mother's treatment. In this respect the Bill mirrors the legal provisions that apply to married couples.

Clauses 43 and 44 would deal with the position of female partners who are not in a civil partnership and would mirror the provisions for heterosexual partners who are not married. Where one of the women has a child following assisted reproduction in a licensed clinic in the UK, then the other woman would be the legal parent if they have notices of consent in place at the time of the embryo or sperm and eggs being placed in the mother.

Clause 53 would specify when references to a child's father in legislation would be read as references to a woman who is treated as the child's parent by virtue of the Bill's provisions relating to parenthood in same sex couples.

"Deceased parents"

Clause 39 would replace provisions inserted into the HFE Act by the *Human Fertilisation and Embryology (Deceased Fathers) Act 2003* and would apply when a man's sperm, or

¹²⁸ [Civil Partnership Act 2004](#)

¹²⁹ Women and Equality Unit webpage: [Civil partnerships](#) [on 2 May 2008]

an embryo created with it, is used after his death. The man could, in these circumstances, be treated as the child's father for the purposes of birth registration providing that:

- he consented, in writing, to the use of the sperm or embryo after his death
- he consented, in writing, to being treated as the child's father for the purposes of birth registration
- the woman has elected, in writing, and within 42 days of the child's birth, that the man be treated as the child's father for birth registration

Where donated sperm has been used, **clauses 40 and 46** would enable the mother's deceased husband, civil partner, heterosexual partner or same sex partner to be registered as the parent of a child, provided certain conditions are met.

c. *Debate on the Bill in the House of Lords*

Including the fact of donor conception on birth certificates

At Committee Stage in the House of Lords, the issue of whether the birth certificate of a donor-conceived person should have that fact recorded on it was debated at some length. An amendment to this effect, which was eventually withdrawn, was moved by Earl Howe, the Conservative Spokesperson for Health.¹³⁰

Earl Howe noted, and recognized the force of the argument, that "families with donor-conceived children should be free to manage for themselves the whole business of whether and how to tell a child of his genetic origins, and that the state should not take action to, effectively, force the hand of such parents to convey this information to children".¹³¹ However he went on to give his reasons for believing that birth certificates should include the fact of donor conception. One of these concerned human rights: he considered that every child has the right to know or to find out who his or her parents are.¹³²

Another reason given by Earl Howe concerned a person's sense of identity:

A person's sense of identity is bound up in very large measure with their personal history and a knowledge of where they came from. A birth certificate that omits any mention of donor conception falsifies that history in a profound way...I do not believe that it would be acceptable or right to place a legal duty on parents to tell children about the circumstances of their birth. However, we can give parents the strongest possible motivation for finding an appropriate way of letting a child know before he finds out for himself.¹³³

Earl Howe suggested that two birth certificates could be issued for a donor conceived child. There could be a full birth certificate containing a note indicating the fact of donor conception. A shorter certificate would not contain this note and could be used when a

¹³⁰ HL Deb 10 December 2007 c91

¹³¹ HL Deb 10 December 2007 c91

¹³² HL Deb 10 December 2007 cc91-2

¹³³ HL Deb 10 December 2007 c92

person did not want to reveal that they were donor conceived (for example, when opening a bank account).¹³⁴

Baroness Barker, the Liberal Democrat Spokesperson for Health, observed that officials increasingly ask for long birth certificates and therefore proposed an amendment “to try to build in a degree of protection and privacy”: this would be for a symbol on a birth certificate to indicate donor conception.¹³⁵ The cross bench peer, Baroness Warnock, supported Baroness Barker’s amendment and commented during the debate:

...one of the greatest immoralities is to keep up a long-term deception of a child as to his origins. My preferred solution has long been simply to have “by donation” on the birth certificate. I fully understand that people may not want to produce this when they are opening a bank account or whatever, and therefore I support the amendment of the noble Baroness, Lady Barker, as a compromise. I think it is a very good compromise on which people can agree, but I also regard it as a temporary compromise because I believe that attitudes are changing. If people learn somehow or other that this information appears, even if it is kept aside from the actual birth certificate by means of a symbol, or a circle, or a picture of a devil, or whatever, that symbol will soon become just like a word. One will know how to interpret it: it will just mean “by donation”.¹³⁶

The Labour peer, Baroness Hollis of Heigham, also noted that “a coded symbol on the birth certificate would be read as ‘donor conceived’ very quickly” and that “abbreviated birth certificates in the public domain are increasingly unacceptable”.¹³⁷ She therefore wondered whether a pair of “long” birth certificates might be possible:

one with the information [about birth through donor conception] and one without, with the full information being sent to the young person at the age of 18 and parents then being notified that it will be coming. That young person can then choose which of the two birth certificates to deploy in what situation. They would have the information in reserve on a full certificate if they wished and needed to use it.¹³⁸

Baroness Royall of Blaisdon, the Government Whip, Spokesperson for Health, for International Development, and for the Foreign and Commonwealth Office, agreed that it was important that donor conceived children should be told of their origins:

...our policy is one of openness in this area. Whether birth certificates should be annotated in some way to indicate donor conception is not a new issue; indeed the Warnock committee concluded in 1984 that,

“we are of the view that consideration should be given as a matter of urgency to making it possible for the parents in registering the birth to add ‘by donation’ after the man’s name”

¹³⁴ HL Deb 10 December 2007 cc92-3

¹³⁵ HL Deb 10 December 2007 cc95-6

¹³⁶ HL Deb 10 December 2007 c99

¹³⁷ HL Deb 10 December 2007 cc102-3

¹³⁸ HL Deb 10 December 2007 c103

That recommendation was rejected at the time. As far as the Government are aware, no other country in the world puts “by donor” on children’s birth certificates.

The Government have long believed that it is of prime importance that donor-conceived children are made aware, from a young age, of their background and are committed to encouraging that...we are currently having discussions with the Donor Conception Network—an organisation of families of donor-conceived children and donor-conceived adults—about ways in which current and potential parents of donor-conceived children can be encouraged to tell the children about their origins.¹³⁹

Baroness Royall resisted both Earl Howe’s amendment and Baroness Barker’s amendment.¹⁴⁰

At Report Stage, the Conservative peer, Lord Jenkin of Roding, tabled an amendment which would have enabled the Human Fertilisation and Embryology Authority (HFEA) to carry out a review of the law and practice concerning the inclusion of donor conception on birth certificates. The amendment also proposed that if, after such a review, and after consultation with bodies representing donor conceived persons, the HFEA recommended the law to be changed, then the Secretary of State would lay a draft order implementing the recommendations, subject to the affirmative procedure.¹⁴¹

Lord Jenkin noted that organisations representing donor conceived people often have “deeply opposed and strongly held views” on whether to indicate donor conception on birth certificates.¹⁴² He believed that his amendment offered a “reasonable way forward”.¹⁴³ To illustrate this he outlined the views of the International Donor Offspring Alliance (IDOA) and the Donor Conception Network. The IDOA “feels strongly that the fact of donor conception should be recorded on the birth certificate” while the Donor Conception Network “warmly welcomes the objective and believes that donor-conceived children should be told, but believes that recording the fact of donor conception on the birth certificate is not the right way to achieve that”.¹⁴⁴

Baroness Barker, arguing against the amendment, observed that the IDOA and Donor Conception Network “do not represent all shades of opinion on the matter” and that many people born as a result of donor conception “feel strongly that singling out one group of children in a public manner [through a birth certificate]...is utterly wrong”.¹⁴⁵ She was also concerned at what would trigger a review by the HFEA and that the matter could be “swayed by changes in public opinion based on one or two cases”.¹⁴⁶

¹³⁹ HL Deb 10 December 2007 c104

¹⁴⁰ HL Deb 10 December 2007 c104

¹⁴¹ HL Deb 28 January 2008 cc501-2

¹⁴² HL Deb 28 January 2008 c504

¹⁴³ HL Deb 28 January 2008 c504

¹⁴⁴ HL Deb 28 January 2008 c502

¹⁴⁵ HL Deb 28 January 2008 c508

¹⁴⁶ HL Deb 28 January 2008 cc508-9

Baroness Royall, replying for the Government, resisted the amendment. She commented that it would be better for a person to find out that they are donor conceived “in the course of a discussion with his or her family rather than through a birth certificate”, particularly as recording donor conception on a birth certificate would mean that the information would not be kept private.¹⁴⁷ Another concern was whether the HFEA, as proposed in the amendment, would be best placed to carry out a review.¹⁴⁸

Lord Jenkin withdrew his amendment but at Third Reading he tabled another amendment in an attempt to find a “way forward”. He proposed that within four years of Schedule 6 of the Bill coming into force, the Secretary of State would carry out “a review of the law and practice” on whether to include donor-conception on birth certificates.¹⁴⁹

Baroness Royall again resisted the amendment, but made a commitment that the Government would carry out a review:

I can make a firm commitment that the Government will carry out a review of practices in informing donor-conceived children of the fact of their donor conception and whether there is a need for a change in the law to best ensure that donor-conceived children are informed of their donor conception. We will do this within the timeframe suggested by the amendment tabled by the noble Lord, Lord Jenkin.¹⁵⁰

Lord Jenkin withdrew his amendment.

Female civil partners on birth certificates

Schedule 6, paragraphs 1 to 9, of the Bill would include detailed amendments to the *BDRA 1953* to give effect to the provisions of the Bill concerning the registration of female civil partners as parents. In Committee, the cross bench peer, Baroness Deech, moved an amendment that would have removed these paragraphs from the Bill:

We are talking about a birth registration in these clauses, not a record of the legal relationship between the adults. It is the welfare of the child that is paramount in English law, not the formal benefits that might accrue to the parents. Using birth certificates to record the adult relationship is not the way to certify the relationship between two people of the same sex or to secure their obligations to the child. Paragraphs 1 to 9 of Schedule 6 provide for two women—and it would have to include two men as well—to be registered as parents on a birth certificate and for the legitimacy of the offspring.

In an earlier set of amendments your Lordships considered without much favour the notion of marking a birth certificate with the information that the child was conceived by donor gametes. The arguments against that amendment were the invasion of privacy and the interference with parental concerns about when and what to tell a child. The provisions of Schedule 6 regarding the birth certificate suffer from the same problems, which are indeed exacerbated. For without even

¹⁴⁷ HL Deb 28 January 2008 c510

¹⁴⁸ HL Deb 28 January 2008 c510

¹⁴⁹ HL Deb 4 February 2008 c898

¹⁵⁰ HL Deb 4 February 2008 c904

the slight disguise provided by a symbol, it will be immediately apparent to anyone perusing the certificate that the child was born either from donor sperm or a donor embryo or to a surrogate mother...

(...)

This schedule confuses biological genetic parenthood and legal social parenthood...¹⁵¹

Later on in the Committee debate, Baroness Deech noted that “[birth] certificates are used for all purposes and in an increasingly globalised world will be used all over the world as proof of this and that”. Birth certificates should therefore focus “on the child’s origins, not the situation of the parents”.¹⁵²

Baroness Barker disagreed with Baroness Deech and argued that a birth certificate is not a certificate of somebody’s genetic identity:

it is a record of who a child’s social parents are at any time. Therefore, since the passage of the Civil Partnership Act, it is possible for children to have two parents of the same sex. Those people take on the legal responsibility, social welfare responsibility, and all sorts of things, such as medical decision-making, which go on throughout the life of a child. That life is more important than the moment of their birth being recorded, which is why having an annotation of their family is important.¹⁵³

She also argued that on the “logic” of the amendment, the *Civil Partnership Act 2004* would have to be repealed and the sexual orientation regulations overturned.¹⁵⁴

The Bishop of Winchester argued that this would not be the case and went on to say:

Given a choice between disagreeing with what is a fiction in relation to the child and the question of the current adult relationship, it seems to me that we must follow the proposal to remove these paragraphs from the Bill and not create a fiction about the child. I believe that the noble Baroness, Lady Deech, is right in saying that that is what a birth certificate fundamentally relates to.¹⁵⁵

Replying for the Government, Baroness Royall resisted the amendment:

...while the Civil Partnership Act provided for the acquisition of parental responsibility, it did not provide for civil partners to be joint legal parents following assisted conception with donor sperm, for both partners to be legal parents of that child or for that fact to be recorded on birth certificates. The Bill allows that same-sex couples, whether in a civil partnership or being treated together, can both be legal parents of a child born through assisted conception. For these provisions to be fully legally recognised, the Bill includes amendments to other Acts to allow birth certificates under UK, Scottish and Northern Irish law to record that.

¹⁵¹ HL Deb 12 December 2007 cc289-91

¹⁵² HL Deb 12 December 2007 c297

¹⁵³ HL Deb 12 December 2007 c299

¹⁵⁴ HL Deb 12 December 2007 c293

¹⁵⁵ HL Deb 12 December 2007 c293

I understand that some see as a fallacy recording on a birth certificate that a child has a mother and a second parent who happens to be female. However, I must point out that a child born to a married couple by the use of donor sperm has recorded on his birth certificate that the husband is his father, although he is in fact not his biological father. Currently, if a same-sex female couple have a child as a result of assisted conception, only the mother's name will go on the birth certificate. If the second parent then goes through the process of adopting the child, a new birth certificate will be produced that has the mother's name and the name of the second parent. Therefore, having the name of a mother and a second female parent on a birth certificate is not a new concept in birth registration.¹⁵⁶

Baroness Deech withdrew her amendment.

G. Payments for surrogacy services

Part 3 of the Bill deals with the commercialisation of surrogacy. If a woman cannot carry a child for medical reasons she is able to ask another woman to be a surrogate mother and carry a child for them. The law on surrogacy is set out in the *Surrogacy Arrangement Act 1985*, and the HFE Act and the main points of these Acts include:

- Agencies or individuals are prohibited from acting on a commercial basis to initiate, negotiate or compile information towards the making of a surrogacy arrangement.
- The legislation does not prohibit non-commercial agencies, nor does it prohibit payment to a surrogate mother.
- Surrogacy contracts are unenforceable in law.
- Any centre offering in vitro fertilisation or donor insemination as part of a surrogacy arrangement must be licensed by the Human Fertilisation and Embryology Authority.
- A competent court can make a 'parental order' making the intended parents in a surrogacy arrangement the legal parents of the child.

Further information on the regulation of surrogacy can be found on the BMA website.¹⁵⁷

The *Human Tissue and Embryos (Draft) Bill* presented the Government's proposals to allow non-for-profit organisations to receive payments for carrying out activities in two categories; initiating negotiations with a view to making a surrogacy arrangement; and compiling information about surrogacy. The Joint Committee on the draft Bill provided the following comment on the evidence they received on these provisions:

287. We received evidence from a number of witnesses, mainly faith-based organisations, who were against surrogacy *per se* and therefore against the provisions in the draft Bill. Others raised specific areas of concern in relation to surrogacy. In particular, several echoed the concerns of Professor Brenda

¹⁵⁶ HL Deb 12 December 2007 cc296-7

¹⁵⁷ BMA webpage: [Considering surrogacy? Your questions answered](#) [on 2 May 2008]

Almond, that advertising and the payment of a range of fees represented “a step towards commercialising surrogacy”. Comment on Reproductive Ethics (CORE) argued that the procedures entailed “significant risks” for the women involved.

288. Others, however, were more positive about the provisions in the draft Bill. Professor Sir Ian Kennedy felt that the balance between maintaining an appropriate response to infertility for some couples on the one hand and prohibiting commercialisation of the practice on the other “does seem about right”. (Ev108) Professor Margaret Brazier, from the Centre for Social Ethics and Policy, School of Law, University of Manchester, argued that clause 66 simply sought to legitimise current practices in surrogacy but expressed concern about “legitimising the role of surrogacy agencies without any process for registering or controlling such agencies” (Ev109, question 10). The British Association of Social Workers Project Group on Assisted Reproduction (PROGAR) and the British Association for Adoption and Fostering similarly argued that such agencies should be formally registered with the regulator.

289. We support the balance that the draft Bill is trying to achieve, but we do not think it goes far enough to protect both children born as a result of surrogacy and surrogate mothers. **We recommend that the draft Bill be amended to bring the regulation of surrogacy within the remit of the HFEA.**¹⁵⁸

In their response, the Government committed to examine the potential of transferring surrogacy regulation to the HFEA.

The potential regulation of surrogacy raises a host of issues that require careful consideration, in particular weighing up the benefits and disadvantages of introducing additional regulation. The Government intends to follow up this recommendation by consulting with stakeholders to assess the possible benefits that regulation of surrogacy may bring, the detail of what regulations may cover, and the scope and structure of any regulatory regime, while taking into account the principles of better regulation.¹⁵⁹

a. The Bill

Clause 59 of the *Human Fertilisation and Embryology Bill* would allow non-for-profit organisations to be paid for providing some surrogacy services. The Explanatory Notes explain which services this may apply to:

251. The clause separates out into four categories the activities which are prohibited if done on a commercial basis. Not-for-profit bodies are permitted to receive payment for carrying out activity in two of those categories. The first is initiating negotiations with a view to the making of a surrogacy arrangement. A non-profit making body might charge, for example, for enabling interested parties to meet each other to discuss the possibility of a surrogacy arrangement between them. The second is compiling information about surrogacy. Not-for-profit organisations would, for example, be able to charge for establishing and keeping

¹⁵⁸ Joint Committee on the Human Tissue and Embryos (Draft) Bill, *Human Tissue and Embryos (Draft) Bill Report* 1 August 2007 HL 169-I/HC630-1 2006-07

¹⁵⁹ [Government Response to the Report from the Joint Committee on the Human Tissue and Embryos \(Draft\) Bill](#), CM 7209 8 October 2007

lists of people willing to be a surrogate mother, or intended parents wishing to have discussions with a potential surrogate mother.

252. It will remain the case that not-for-profit bodies will not be permitted to receive payment for offering to negotiate a surrogacy arrangement or for taking part in negotiations about a surrogacy arrangement. These activities are not unlawful if there is no charge, however.¹⁶⁰

It is currently an offence to advertise that someone may be willing to enter into a surrogacy arrangement. The Bill would also allow not-for-profit bodies to advertise that they hold a list of people seeking surrogate mothers and a list of people willing to be involved in surrogacy.

H. Abortion

The Government is not seeking to change the abortion laws using the *Human Fertilisation and Embryology Bill*. However, amendments to abortion law may be accepted during the passage of the Bill, as the *Abortion Act 1967* was amended by the *Human Fertilization and Embryology Act 1990* (the HFE Act),¹⁶¹ which the Bill is to amend. Both pro-choice and pro-life groups are lobbying for changes to either liberalise or tighten the current abortion legislation. The Joint Committee on the draft Bill did not consider this issue in depth.¹⁶²

We were advised by the Clerk of Public Bills in the House of Lords and the Clerk of Legislation in the House of Commons that, if a Bill in terms similar to the Draft Bill were to be introduced, amendments relating to termination of pregnancy (abortion), the retention of tissue samples and presumed consent for organ donation would in principle be orderly. While we recognise that these are important issues, we took a decision at the start that abortion and presumed consent for organ donation would not form a specific part of our inquiry because they do not form part of the Draft Bill. We do cover the retention of tissue samples in Chapter 5.

We also acknowledge there are other important issues relevant to the debate, in particular recent developments in adult stem cell research, but again these have not formed part of our inquiry. We note that during our inquiry, the House of Commons Science and Technology Select Committee¹⁶³ announced an inquiry into Scientific Developments relating to the Abortion Act 1967.

1. Current abortion legislation

The *Abortion Act 1967* came into effect on 27 April 1968. This permits abortion in Great Britain (not including Northern Ireland) by registered practitioners subject to certain conditions. Section 37 of the HFE Act made changes to the Abortion Act. It introduced a

¹⁶⁰ [Explanatory Notes to the Human Fertilisation and Embryology Bill](#)

¹⁶¹ *Human Fertilisation and Embryology Act 1990* section 37

¹⁶² Joint Committee on the Human Tissue and Embryos (Draft) Bill, Report 1 August 2007 HL 169-I/HC630-1 2006-07, Paragraph 2

¹⁶³ House of Commons Science and Technology Select Committee, [Terms of reference-Scientific developments relating to the Abortion Act 1967](#)

time limit of 24 weeks for grounds C and D. Grounds A, B and E are now without limit. Before this change, a 28-week limit had applied for all grounds. The HFE Act also confirmed that when a woman had a multiple pregnancy it was legal for a doctor to terminate the life of one or more foetuses leaving others alive.¹⁶⁴

Over 98% of abortions are performed under grounds C and D.

Grounds for permitting abortions under the current UK legislation

A - the continuance of the pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy were terminated

B - the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman

C - the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman

D - the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of any existing child(ren) of the family of the pregnant woman

E - there is substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped

Or in emergency, certified by the operating practitioner as immediately necessary:

F - to save the life of the pregnant woman

G - to prevent grave permanent injury to the physical or mental health of the pregnant woman

The *Abortion Act* is unusual in its provision of a 'conscience clause'. By giving doctors the ability to opt out of their involvement in the procedure it acknowledges the deep division of views within the medical profession. Abortion legislation is also unusual as successive governments have decided that any further change should be left to a free vote by MPs.

This Government decided not to consider abortion in its recent review of the *Human Fertilisation and Embryology Act*.¹⁶⁵

2. DoH test sites

The *Abortion Act 1967* dictates that abortion may only be carried out in licensed premises¹⁶⁶

¹⁶⁴ British Pregnancy Advisory Service (bpas): [Abortion webpage](#) [on 2 May 2008]

¹⁶⁵ Department of Health, *Review of the Human Fertilisation and Embryology Act, Proposals for revised legislation*, CM 6989, December 2006

¹⁶⁶ [Abortion Act 1967](#): Ministry of Justice statute law database

...any treatment for the termination of pregnancy must be carried out in a hospital vested in [the Secretary of State for the purposes of his functions under the National Health Service Act 1977 or the National Health Service (Scotland) Act 1978 [or in a hospital vested in [a Primary Care Trust or] a National Health Service trust] or in a place approved for the purposes of this section by the Secretary of State]

[(3A) The power under subsection (3) of this section to approve a place includes power, in relation to treatment consisting primarily in the use of such medicines as may be specified in the approval and carried out in such manner as may be so specified, to approve a class of places.]

The Government confirmed that it is piloting performing abortions in non-traditional settings in the document

[Government Response to the Report from the House of Commons Science and Technology Committee on the Scientific Developments Relating to the Abortion Act 1967](#), 29 November 2007, Cm7278

Places where abortions can be carried out

21. We conclude that, subject to providers putting in place the appropriate follow up arrangements, there is no evidence relating to safety, effectiveness or patient acceptability that should serve to deter Parliament passing regulations which would enable women who chose to do so taking the second stage of early medical abortion at home, or that should deter Parliament from amending the act to exclude the second stage of early medical abortion from the definition of “carrying out a termination”. This would enable a trial to take place. (Paragraph 123)

22. We invite Members of Parliament to consider our conclusions when considering the question of whether the 1967 Act should be amended or regulations passed to enable the second stage of early medical abortion to be self-administered in a woman’s home. (Paragraph 124)

We note the Committee’s recommendations.

Under the Abortion Act 1967, an abortion (surgical and medical) can only be performed in a hospital vested in an NHS trust, PCT or foundation trust or in an approved independent sector place. Section 1(3A) of the Abortion Act 1967 also gives the Secretary of State the power to approve a class of place to perform medical abortion which could enable this method to be available in a wider range of healthcare settings. This provision has not yet been used in England as we are awaiting the outcome of work to determine what any particular “class of place” should be.

Two hospitals are currently being funded by the Department of Health to run early medical abortion services in non-traditional settings, to evaluate the effectiveness and safety of provision in these settings.

A formal evaluation is under way to assess the safety, effectiveness and patient acceptability of providing early medical abortion services in non-traditional settings. The evaluation will be complete in the New Year and we will consider the results carefully.

The Government was responding to the Science and Technology Committee's report [Scientific Developments Relating to the Abortion Act 1967](#) dated 31 October 2007.

3. Ethical issues

The views of the medical establishment have been inclined to become increasingly permissive of abortion over time, as demonstrated by these statements.¹⁶⁷

- I will not give to a woman a pessary to produce abortion. *Hippocratic Oath*
- I will maintain the utmost respect for human life from the time of conception even against threat. *The Declaration of Geneva, World Medical Association, 1948*
- The spirit of the Hippocratic Oath can be affirmed by the profession. It enjoins... the duty of caring, the greatest crime being the co-operation in the destruction of life by murder, suicide and abortion. *BMA statement, 1947*
- The child deserves 'legal protection before as well as after birth'. *The UN declaration of the rights of the child, 1959*
- Therapeutic abortion [may be performed in circumstances] where the vital interests of the mother conflict with those of the unborn child. *Declaration of Oslo, World Medical Association, 1970*
- I will maintain the utmost respect for human life from its beginning... *Amended Declaration of Geneva, World Medical Association, 1983*
- Abortion is a basic health care need. *Royal College of Obstetrics and Gynaecology, 2000*

a. Pro Choice

The main argument of the pro choice lobby is that a woman has a right to choose whether or not to have an abortion, and therefore must have access to safe controlled abortions. They believe that the birth of unwanted children leads to harm – to society, families and women themselves. There is an All-Party Parliamentary Pro-Choice and Sexual Health Group, with the aim: To raise awareness in parliament of the needs of women seeking abortion and the importance of improving all aspects of the sexual health of women and men in the UK (funded by the Family Planning Association).

b. Pro Life

Pro life campaigners are usually, but not exclusively, from a religious background. Their belief is that the foetus has moral status as a human being and therefore abortion is killing. A religious belief in the sanctity of life reinforces that viewpoint. There is an All-Party Parliamentary Pro-Life Group, with the aim: To provide a forum for discussion of pro-life issues including abortion, euthanasia and research upon the human embryo (funded by Christian Action Research and Education (CARE) and Right to Life).

¹⁶⁷ Christian Medical Fellowship website ["Abortion" Ethics briefing](#) [on 2 May 2008]

c. Other Positions

Many do not align themselves wholly with either of the above groups, but are still unhappy with the current situation in the UK. Here are some of the most common complaints

- ***The current upper age limit for the foetus is too high***

The 24 week rule, under which a vast majority of abortions under grounds C&D above are carried out, is now deemed by some to be too “old”. Advances in neonatal care mean that babies can survive outside the womb, in some cases, from 21 weeks. More detailed scanning techniques, showing foetuses as “more human” also add weight to the argument to prevent abortions under grounds C&D where the gestational age of the foetus is greater than 24 weeks or even lower. Questions of viability and sentience are the subject of ongoing research, and debate over definitions.

The inclusion of this age limit rule, and arguments around it, are based on the ethical argument that the foetus gains moral status as a human as it becomes capable of life outside the womb.

The Science and Technology Committee looked into this issue in much detail, and published a report on its findings (see section 4 below).¹⁶⁸

- ***The law is not correctly applied***

The actual provisions of the law do not really relate to the reality of its application. Grounds C&D are the “loosest” of all the sections and therefore most abortions are undertaken in those groups. Critics argue that the abortion law would be acceptable, if only grounds C&D were properly applied. They would say that “I just couldn’t cope with a child right now” is not a sufficiently strong argument to support the provisions of ground C:

“.....the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman.....”

The nature of the term “serious handicap” (ground E) has also been brought into question.¹⁶⁹

In 2003, Rev Joanna Jepson sought a judicial review of the decision of the Chief Constable of West Mercia Police Constabulary not to pursue a prosecution of doctors who terminated a pregnancy at more than 24 weeks’ gestation, where the foetus had been diagnosed with bilateral cleft lip and palate. The police authorities had undertaken an investigation of the case and were satisfied that the abortion was legally justified and properly carried out.

¹⁶⁸ Science and Technology Committee, [Scientific Developments Relating to the Abortion Act 1967](#), 31 October 2007, HC 1045-1 2006-07

¹⁶⁹ BMA, [EthicsBrief issue 75](#), June 2005

Rev Jepson challenged this decision on the basis that bi-lateral cleft lip and palate was not a 'serious handicap' and therefore the abortion had been unlawful. Rev Jepson was granted permission for a judicial review but subsequent to that decision the police re-investigated the case and sent a file to the Crown Prosecution Service (CPS). The CPS announced in March 2005 that the doctors involved would not face prosecution. The Chief Crown Prosecutor for West Mercia CPS, Jim England, said that the doctors had decided in good faith that a substantial risk existed that the child would be seriously handicapped if born. In April 2005 it was reported that Rev Jepson was planning to revive her judicial review proceedings.

- ***The current law does not allow a woman to choose for herself***

The current regulations require two doctors to see, counsel and agree with the woman that she requires an abortion under one of the conditions mentioned above. Pro choice campaigners would argue that this is an infringement of a woman's right to choose, and the two doctor signature should not be a requirement. Indeed there are arguments from pro choice groups that doctors need not be involved in many abortions at all, and suitably qualified nurses would be suitable for most steps of the abortion process.

4. The Science and Technology Select Committee

This Committee published the report *Scientific Developments Relating to the Abortion Act 1967* on November 1st 2007.¹⁷⁰ It was a controversial inquiry, with claims of selective evidence, bias and conflict of interests from both sides. The Committee did not agree on a unanimous report – the minority report was published as an appendix.

¹⁷⁰ House of Commons Science and Technology Committee. *Scientific Developments Relating to the Abortion Act 1967*, 1 November 2007, HC 1045-I

Appendix 1: Parliament and Government reports and resources list

[Human Tissue and Embryos \(Draft\) Bill, May 2007](#)

[Human Tissues and Embryos \(Draft\) Bill Joint Committee report, August 2007](#)

[Government Response to the Report from the Joint Committee on the Human Tissue and Embryos \(Draft\) Bill, October 2007](#)

Department of Health:

[Department of Health: Bill information](#)

[Review of the Human Fertilisation and Embryology Act: A public consultation](#)

Launch date: 16 August 2005 Closing date: 25 November 2005

[Consultation response document:](#) 29 March 2006

[Review of the Human Fertilisation and Embryology Act: proposals for revised legislation \(including establishment of the Regulatory Authority for Tissue and Embryos\)](#) 14 December 2006

Human Fertilisation & Embryology Authority

[Hybrids and Chimera: A consultation on the ethical and social implications of creating human/animal embryos in research](#) April 2007

[HFEA statement on its decision regarding hybrid embryos](#) 5 September 2007

Science and Technology Committee Reports

[24 March 2005 Eighth Special Report: Human Reproductive Technologies and the Law HC 491](#)

[24 March 2005 Fifth Report: Human Reproductive Technologies and the Law HC 7-I HC 7-II](#)

[16 Aug 2005: Human Reproductive Technologies and the Law: Government Response to the Report from the House of Commons Science and Technology Committee](#)

[5 April 2007 Fifth Report: Government proposals for the regulation of hybrid and chimera embryos HC 272](#)

[18 June 2007: Government Response to the Report from the House of Commons Science and Technology Committee: Government proposals for the regulation of hybrid and chimera embryos](#)

Appendix 2: Legislation concerning stem cell research in other countries

For an overview of embryo research policy in different countries, the University of Minnesota website gives a broad overview.¹⁷¹

Russia

The European Society of Human Reproduction and Embryology describes the legal situation in Russia:

Research on embryos in vitro is allowed. There are not any specific restrictions as for experiments on a human embryo imposed by any law or act. No ethics committee approval is required. There is not any specific federal law or regulation regarding embryo research in Russia. The only document that regulates ART in Russia is Order 67th of the RF Ministry for Health (Reg. №4452 24.04.03 RF Justice Ministry). This regulation deals with basic aspects of IVF, AI, gamete and embryo donation, surrogacy, PGD, but it does not even mention embryo research.

So creation of embryos in vitro for research purposes is not forbidden, as well as use of embryos left after successful IVF procedure for scientific purposes. Written informed consent for ovarian stimulation and further use of embryos is always mandatory.

Cryopreservation of embryos is allowed and sometimes even recommended. Preimplantation diagnosis and sex selection are allowed only when there is a risk of giving birth to children with hereditary pathologies (gene mutations or chromosomal anomalies), as an alternative method for prenatal diagnosis - to prevent gender-linked hereditary diseases.¹⁷²

Italy

In Italy, Law n.40 (19/2/2004), Regulation of Medically Assisted Reproduction Embryo Research governs embryo research. Article 1 attributes the human embryo the right of a person from the moment of fertilization. Article 13 specifically governs embryo research:

Art. 13 - Research on human embryos.

1. Any experiment on a human embryo is prohibited.
2. Clinical and experimental research on each human embryo is only permitted on condition that it solely aims to reach therapeutic and diagnostic goals related to the health and development of the embryo itself, and if no other alternative procedure is available.

¹⁷¹ [University of Minnesota website](#) (on 2 May 2008)

¹⁷² European Society of Human Reproduction and Embryology webpage: [Russian legislation - Embryo research](#) [on 2 May 2008]

3. The following conditions are anyway banned:
 - a. the production of human embryos for research or experiment or anyhow for purposes different from those stated in this Law;
 - b. every form of eugenic selection of embryos and gametes, namely any procedure that, through selection techniques or manipulation or any artificial method, is directed at the alteration of the genetic inheritance of the embryo or gamete, or at the predetermination of its genetic characteristics, with the exception of the procedures performed for diagnostic and therapeutic purposes mentioned in clause 2 of this article;
 - c. procedures of cloning through nuclear transfer or early embryo splitting or of ectogenesis both for reproductive and research purposes;
 - d. the insemination of a human gametes by gametes from different species and the production of hybrids and chimeras.
4. The violation of the prohibitions mentioned in clause 1 is punished with 2 to 6 years imprisonment and with a penalty of 50.000 to 150.000 euros. In case of violation of one of the prohibitions of clause 3, the sanctions will be increased.
5. Any health professional condemned for any of the crimes mentioned in this article will be suspended from professional practice for a period of 1 to 3 years.

France

The European Society of Human Reproduction and Embryology describes the legal situation in France:

Legal framework:

- Law no. 2004-800, August 6th 2004, relating to bioethics
- Decree no. 2006-126, February 6th 2006, relating to research on embryos and embryonic cells

Article L.2151-1 of the Public Health Regulations: The conception of an embryo in vitro or its constitution by human embryo cloning for research purposes is prohibited.

Article L. 2151-5: In principle, research on embryos is prohibited.

However, exceptionally, if the woman and man forming the couple give their consent, studies not damaging the embryo may be authorised provided that certain conditions are respected. By special dispensation, and for a period limited to five years (beginning on February 7th 2006), research may be carried out on embryos and embryonic cells if such research is likely to lead to major progress in the development of treatments and provided that it could not have been carried out by an alternative method of comparable efficacy, based on current scientific knowledge.

Research can only be carried out on embryos conceived in vitro by assisted reproductive technology, and which are no longer required by the parents. Such research can only be carried out if and after both members of the couple from

which the embryo was created provide written consent or if and after such consent is obtained from the sole survivor of that couple, once these individuals have been duly informed of the possibility of donating their unwanted embryos to another couple or of stopping their storage.

Research can only be carried out if the corresponding protocol has been authorised by the Biomedicine Agency, based on expert advice. The decision to authorise embryo research is based on the scientific pertinence of the research project and the conditions under which it will be carried out, taking into account both ethical principles and the interests of public health.

The embryos used for research must not be transferred for the purposes of gestation.

Article L. 2151-6: The importation and exportation of embryonic and foetal tissues and cells for research purposes is subject to prior authorisation from the Biomedicine Agency.

Article L. 2151-7: All organisations responsible for storing embryonic stem cells for scientific purposes must hold an authorisation from the Biomedicine Agency.¹⁷³

Norway

The relevant law in Norway is the Act of 5 December 2003 No. 100 relating to the application of biotechnology in human medicine, etc. Embryo research is dealt with in Chapter 3, Research on fertilized eggs, cloning and more:

3-1. Prohibition of research on fertilized eggs and more

It is forbidden to do research on human embryos and cell lines cultured from human embryos.

3-2. Forbidding the creation of human embryos by cloning and more.

It is forbidden to:

- Create human embryos by cloning.
- Do research on cell lines cultured from human embryos by cloning and
- Create embryos by cloning with human genetic material into egg cells of animals.

By cloning is meant techniques for the creation of genetically identical individuals.

3-3. Prohibition of techniques intended for the creation of genetically identical individuals.

It is forbidden to use techniques intended for the creation of genetically identical individuals.¹⁷⁴

¹⁷³ European Society of Human Reproduction and Embryology webpage: [French legislation - Embryo research](#) [on 2 May 2008]

¹⁷⁴ [Act of 5 December 2003 No. 100 relating to the application of biotechnology in human medicine, etc](#)

Spain

The relevant law in Spain is Law 14/2006; 27th May 2006. BOE nº 126, Embryo Research:

CHAPTER IV

Research using human gametes and pre-embryonic cells

Article 14. Use of gametes for scientific research.

1. Individual gametes can be used for research purposes.
2. Gametes used for research purposes or experimentation cannot subsequently be implanted into a woman or be used to create pre-embryos for reproductive purposes.

Article 15. Use of pre-embryos for scientific research.

1. Research or experimentation using pre-embryos that were created for reproduction purposes, but are subsequently no longer required for such purposes is considered ethically acceptable only if the following apply:

a) Written consent of the couple, or woman alone when applicable, after they have undergone a detailed explanation of the aims of the investigation and its implications. In all cases, the written consent provided must specify the couple's relinquishment or woman's alone when applicable, of all legal and financial claims over the results that could arise directly or indirectly from the investigations being carried out.

b) The pre-embryo must not have been developing in vitro for more than 14 days after fertilisation. Time spent in cryopreservation state need not be counted.

c) Investigation projects related to development and employing of assisted fertilisation techniques must be carried out in authorised centres. In all cases, projects are to be carried out by qualified scientific teams and kept under the control of the competent health authorities.

d) Research or experimentation must be carried out following a correctly presented project plan. The plan must be approved by the competent health authorities, and if the investigation is related to embryonic development or makes use of assisted reproduction techniques, it must be authorised beforehand by the Comisión Nacional de Reproducción Humana Asistida (National Committee of Assisted Human Reproduction). If the research or experimentation is related to the obtention, development and use of cell lines from embryonic stem cells, the competent authority must approve the project, before the investigation can proceed.

e) In the case of pre-embryos being transferred to another research centre, the relationship between the research teams and centres involved in the transfer, and their common interest of whichever nature must be specified in the aforementioned project plan. In these cases the established confidentiality regulations regarding the origin of the embryo must be maintained, alongside the donors freely given consent to use the cells and the relinquishment of all legal and financial claim over the results

2. Once the investigation has been completed, the health authority that approved the research must transfer the results to the Comisión Nacional de Reproducción Humana Asistida (National Committee of Assisted Human Reproduction) or when applicable, the competent authority that approved the investigation.

Article 16. Conservation and use of pre-embryos in research

1. Surplus pre-embryos that have been cryopreserved and for which consent has been given by the donors, or woman alone if applicable, for them to be used for research purposes, are to be stored in corresponding assisted reproduction centres.

2. Before definitive use of the pre-embryo in an investigation can proceed, the written consent of the couple, or woman alone if applicable, from which the pre-embryo has been obtained is required. This is necessary in all instances, whether the embryo is being used following a specific project plan devised by the assisted reproduction centre where it was obtained, or whether it is being used following a specific project plan after its transferral to a different centre. In all cases, the individuals from which the pre-embryo originates must have undergone a detailed explanation and must understand the aims of the research, its stages and duration, the specificity of its restriction to a basic scope or its extension to a wider scope of clinical use, as well as the possible outcomes of the investigation. If written consent has not been given to use a pre-embryo in a specific investigation, it should be requested in all cases before any research starts, unless consent has not been renewed according to the provisions of clause 11.6

Australia

The Australian Stem Cell Centre describes the law relating to embryo research in Australia:

In Australia, there is a piece of legislation covering stem cell research and cloning. This is the Regulation of Human Embryo Research Amendment Act 2006.

The various States and Territories of Australia have their own legislation regulating the use of embryos in research, which seeks to be consistent with the Commonwealth legislation.

There is no legislative framework regulating the use of human stem cells (embryonic or adult) after they have been derived. However, the use of human stem cell lines in research must comply with relevant National Health and Medical Research Council (NH&MRC) guidelines.

When using human embryos for research, scientists must obtain a licence from the NH&MRC.

The Therapeutic Goods Administration in Australia is developing a national regulatory framework for human tissues and emerging biological therapies.¹⁷⁵

United States

The United States National Institutes of Health (NIH) explains the policy in US:

The President's Criteria

On August 9th, 2001, President George W. Bush announced that federal funds may be awarded for research using human embryonic stem cells if the following criteria are met:

- The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001.
- The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
- Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.

NIH's Role

The NIH, as the Federal government's leading biomedical research organization, is implementing the President's policy. The NIH funds research scientists to conduct research on existing human embryonic stem cells and to explore the enormous promise of these unique cells, including their potential to produce breakthrough therapies and cures.¹⁷⁶

Another area of their website explains:

Individual states have the authority to pass laws to permit human embryonic stem cell research using state funds. Unless Congress passes a law that bans it, states may pay for research using human embryonic stem cell lines that are not eligible for federal funding.¹⁷⁷

¹⁷⁵ Australian Stem Cell Centre webpage: [Research in Australia](#) [on 2 May 2008]

¹⁷⁶ United States National Institutes of Health webpage: [Federal Policy](#) [on 2 May 2008]

¹⁷⁷ United States National Institutes of Health webpage: [Stem Cell Information –frequently asked questions](#) [on 2 May 2008]

Appendix 3: Views of some interested groups

This list is by no means comprehensive, but should cover most of the topics brought up by the Bill. It includes most of the organisations that are actively lobbying at the moment, as well as some others who provide useful information.

- The British Medical Association, the representative body of doctors in the UK, with particularly strong views on regulatory issues.¹⁷⁸
- The Institute of Biology, which provides a good overview and explanation of the issues surrounding stem cell research.¹⁷⁹
- The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as possible into healthcare benefits for society.¹⁸⁰
- The Christian Medical Fellowship, representing Christian doctors, and with close links to the Lawyers Christian Fellowship, which comments and campaigns on various aspects of this legislation.¹⁸¹
- Society for the Protection of the Unborn Child. Campaigning on the Bill as it may be able to alter abortion laws.¹⁸²
- Christian Action Research and Education (CARE) is a large Christian campaigning organisation, which encourages public engagement with politics and provides resources and information for Christians wishing to lobby their MP.¹⁸³
- BioCentre, The Centre for Bioethics & Public Policy is a bioethics think tank. Their website contains a good deal of information on bioscience from a public and social policy background.¹⁸⁴
- Abortion Rights is a pro choice organisation, which clearly explains their rationale for abortion law liberalisation.¹⁸⁵
- Nature Insight is an industry sponsored insert into the journal Nature which provides a good overview of the science of stem cell research, including a glossary.¹⁸⁶

¹⁷⁸ British Medical Association webpage: [Human Fertilisation and Embryology Bill Second reading, House of Commons](#) [on 2 May 2008]

¹⁷⁹ Institute of Biology webpage, [Embryos and Stem Cells](#) [on 2 May 2008]

¹⁸⁰ Academy of Medical Sciences webpage: [Inter-species embryos](#) [on 2 May 2008]

¹⁸¹ Christian Medical Fellowship webpage: [Hybrid and chimera embryos unethical and unnecessary says CMF](#) [on 2 May 2008]

¹⁸² Society for the Protection of the Unborn Child webpage: [Human Fertilisation and Embryology Bill Page](#) [on 2 May 2008]

¹⁸³ Christian Action Research and Education webpage: [A Toolkit to prepare for the introduction of the Human Fertilisation and Embryos Bill](#) [on 2 May 2008]

¹⁸⁴ BioCentre webpage: [Human Animal Hybrids & Chimera](#) [on 2 May 2008]

¹⁸⁵ Abortion Rights webpage: [Why women need a modern abortion law and better services](#) [on 2 May 2008]

¹⁸⁶ Nature Insight webpage: [Stem cells](#) [on 2 May 2008]