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Human Fertilisation and Embryology Bill [HL]: Committee Stage Report

This is a report on the Committee Stage of the Human Fertilisation and Embryology Bill in response to a recommendation of the Modernisation Committee in its report on The Legislative Process (HC 1097, 2005-06).

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 provisions in the Bill covering issues of "saviour siblings", "admixed embryos" and "need for a father" and new clauses or schedules relating to abortion were committed to a Committee of the whole House. The remainder of the Bill was scrutinised by a Public Bill Committee.

The Bill was not substantially altered in Committee though Government amendments to the definition of embryos were agreed as were Government amendments on the use and storage of cells from those lacking capacity (either as children or adults) or where the donor can no longer be identified or has died.

Edward White

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Summary of main points

The *Human Fertilisation and Embryology Bill* would update legislation for assisted reproduction and change the regulation and licensing of the use of embryos in research and treatment which is regulated by the Human Fertilisation and Embryology Authority (HFEA). It includes provisions for research on different types of embryos, and proposes changes to definitions of legal parenthood for cases involving assisted reproduction.

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 would not alter abortion law but amendments may be introduced during the passage of the Bill.

The provisions in the Bill covering issues of "saviour siblings", "admixed embryos” and "need for a father" and new clauses or schedules relating to abortion were committed to a Committee of the whole House on 19 and 20 May 2008. The remainder of the Bill was scrutinised by a Public Bill Committee at eight sessions between 3-12 June.

The Bill was not substantially altered in Committee. Government amendments to the definition of embryos were agreed as were Government amendments on the use and storage of cells from those lacking capacity (either as children or adults) or where the donor can no longer be identified or has died.

All Government amendments were agreed to. No opposition amendments were successful.

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I Progress of the Bill

A. Bill summary

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.

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.

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 Bill is in three Parts: Part 1 contains amendments to the *Human Fertilisation and Embryology Act 1990* (HFEA 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.[1]

[1] 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.[2]

Further information on the Bill is available in the Library Research Paper 08/42, written for Second Reading.

Additional material including Amendment Papers and Proceedings is available on the Parliamentary Public Bill Page.

B. Passage through the House

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.

The Bill was read for the first time in the Commons on 5 February 2008 and published the following day as HL Bill 70. Explanatory Notes to this are available.

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2 Explanatory Notes to the *Human Fertilisation and Embryology Bill*

The Second Reading was on 12 May 2008 at which time the Secretary of State for Health, Alan Johnson, set out the aim of the Bill.

> The purpose of the Bill is to ensure that the 1990 Act is revised to keep pace with new avenues of scientific research and to reflect wider change in our society. As with the 1990 Act, the Bill has been the subject of careful consideration and lengthy consultation involving the public, scientists, faith groups and, of course, Members from both sides of the House and from the other place.
>
> In 2004, following reports by the Science and Technology Committee and the expert group convened by the Government to consider how existing legislation could accommodate and regulate new developments in stem cell research, we announced a review of the 1990 Act. A public consultation then took place in 2005, which led to a White Paper in December 2006. The Bill was then published in draft form for scrutiny by a Joint Committee drawn from both Houses. I am grateful to all the right hon. and hon. Members of this House and noble Lords and Ladies from the other place who have given this Bill the benefit of their expertise, including, of course, Baroness Warnock herself, who continues to keep a close eye on the legislation that she so skilfully instigated.[3]

Debate during Second Reading concentrated on the most controversial aspects of the Bill; those relating to "saviour siblings", "admixed embryos", "need for a father" and abortion (see section II A). The Bill was passed at Second Reading on division (Ayes 340, Noes 78).[4] A Programme Motion came at the end of the debate which committed clauses 4, 11, 14 and 23 and Schedule 2 of the Bill covering issues of "saviour siblings", "admixed embryos" and "need for a father" and new clauses or schedules relating to abortion to a Committee of the whole House. The remainder of the Bill was committed to a Public Bill Committee.

II Issues raised in Committee

A. Committee of the Whole House

Contentious aspects of the Bill were discussed in a Committee of the whole House on 19 and 20 May 2008. Free votes were given at this stage by the Labour, Conservative and Liberal Democrat Parties.

1. Admixed Embryos

The Bill includes proposals to clarify policy on the creation of human-animal embryos. These are embryos created using both animal and human material. They can be used to research embryonic stems cells which could potentially be used to treat a range of degenerative illnesses. The Bill will amend the *Human Fertilisation and Embryology Act 1990* to ensure that the creation, storage and use of admixed embryos is regulated by the HFEA.

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3 HC Deb, 12 May 2008, c1066.
4 HC Deb, 12 May 2008, c1161.

a. Restricting Admixed Embryos

A number of amendments were tabled to prevent admixed embryos from being created. Amendment 1, tabled by Edward Leigh was selected to represent this view. He argued that the practice was ethically wrong and medically unproven:

> It is said by those who resist the amendment that we can rely on regulation, but we do not believe that regulation is enough. We believe that the move is a step too far and should therefore be banned. Indeed, the Government support the contention that some things are so ethically dangerous that they should be banned. For instance, the Bill will not allow the use of embryos for sex selection or to allow deaf people to have deaf children. Occasionally, the House makes a firm decision that something is ethically wrong. The House long ago decided, for example, that it did not want better to regulate capital punishment; it simply stopped capital punishment. The amendment is a call for these experiments to be banned.[5]

Mark Simmonds expressed his opposition to the amendment:

> There are three or four key reasons why I do not agree with the amendments that my hon. Friend and others have tabled. The first concerns therapies for illnesses and diseases. As I have said, research is already under way in that area involving cytoplasmic hybrids. There is no doubt that there is a shortage of human eggs for the production of embryonic stem-cell lines and research or that more are needed to enable such research to move faster. I am also keen to ensure that the House understands that there are significant differences between embryonic stem cells and adult stem cells, particularly given the versatility of embryonic stem cells, which can transfer themselves into almost every cell in the body, which adult stem cells currently cannot do.[6]

The above and other similar restrictive amendments were not accepted on division. This included an amendment by Mark Simmonds that would restrict the types of admixed embryos that could be created by preventing "true hybrids".[7]

b. Embryos for Therapy

An amendment tabled by Evan Harris would have provided that embryos and stem cells created under licence from the Human Fertilisation and Embryology Authority could be used in treatments:

> Finally, I turn to amendment No. 31. It is linked with amendment No. 32, which would amend schedule 2. Amendment No. 32 is the key one; it is very important,

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5 HC Deb, 19 May 2008, c22.

6 HC Deb, 19 May 2008, c30 -1.

7 True hybrids or human-animal hybrid embryos are embryos 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. Other admixed embryos include; cytoplasmic hybrids (cybrids), human transgenic embryos, human-animal chimeras. (See Research Paper 08/42, III D 3)

> but I do not have time to give it its due. It would insert a new provision that would enable the HFEA to give a licence for therapy as well as for research. The problem with the current Bill is that if, one day, the research works, and it is possible to derive from embryos stem cells that could be used to treat, say, diabetics by providing new, insulin-producing cells, or Parkinson's disease, it is not clear whether it would be possible to create embryos and use or store them for the purpose of therapy. Clearly, clinical trials are covered by the term "research", so it will be possible to create, store and use an embryo to provide stem cells for use in clinical trials. One cannot keep doing clinical trials once a treatment is known to work; it is unethical to randomise someone to placebo and someone else to a treatment that is known to be effective. At that point, one has to stop trialling, and instead deliver treatment. At that point, it is not clear whether the original embryo, from which the new stem cells are derived, will be covered, under the HFEA, by a licence, because one can get a licence only for treating infertility or for research.[8]

In response, the Minster Dawn Primarolo, set out the Government's opinion that the Bill will license research for treatments. However, legislation to provide that these treatments can be used will need to come at a later stage.[9] The amendment was withdrawn.

c. Definition of Admixed Embryo

A set of successful Government amendments re-defined the term admixed embryo to include any embryo which contains animal and human DNA in which the human DNA is predominant. The Minister explained why this change was required:

> The amendments are a response to the debate in the other place, where clarification of the definitions was sought. The Government amendments add a catch-all category to the definition of human admixed embryos in the Bill, providing further clarity of the scope of the term. In addition to the four precise scientific definitions already in the Bill, that will ensure that all new forms of embryos that may be developed that contain both human and animal DNA will, where the animal DNA does not predominate, fall within the regulation.[10]

2. Saviour Siblings

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 being parents who have one child suffering from a condition which needs a bone marrow transplant. Currently this would involve using in vitro fertilisation (IVF) to create several embryos, then checking the genetic make up of those embryos and implanting one with the desired (or without the undesired) characteristics. The Explanatory Notes to the Bill described the circumstances under which tissue typing would be allowed.[11]

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8 HC Deb, 19 May 2008, c85-6.
9 HC Deb, 19 May 2008, c87.
10 HC Deb, 19 May 2008, c59.
11 Human Fertilisation and Embryology Bill: Explanatory Notes

> 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 by Evan Harris to clarify and extend the use of tissue typing for saviour siblings and to amend the wording of the Bill so that embryos for implantation could be selected against for a greater number of diseases.

In addition amendments were tabled by David Burrows that would prevent the practice of selecting for a saviour sibling.

These amendments were not agreed to. Dawn Primarolo set out the Government's position:

> **Dawn Primarolo:** Let me try to explain the Government's thinking on clause 11 and schedule 2, and on the issues that have been raised.
>
> The Bill sets out five purposes for which embryos can be tested, and a regulation-making power to amend them. One of the purposes is the creation of so-called saviour siblings. As we have observed this evening, that is an issue that provokes very strong feelings in people on both sides of the discussion. Some feel that the creation of a tissue-matched sibling is entirely appropriate to treat an affected child when it is the only treatment option, and that not to allow it would essentially impose a life sentence on the child. Others feel that, despite that, saviour siblings should not be permitted.
>
> Some parents with an affected child whose only treatment option—perhaps because the child has an unusual tissue type—relies on the creation of a tissue-matched sibling would feel very strongly that the Bill's proposals offer a practical solution. Having a child to satisfy a particular need, in this case the treatment of a sick sibling, is not uncommon. As the hon. Member for Beckenham (Mrs. Lait) pointed out so eloquently on Second Reading, no one has a child solely for the child's own purposes. It is often done to satisfy the needs of parents to be parents, or the need for a brother or sister for an existing child.
>
> Let us consider a family who are in that position. The parents love the existing child so much, and are so motivated to do whatever they can to protect that child, that they are willing to undertake embryo testing. Embryo testing is an invasive and expensive procedure, and such motivated parents are highly unlikely to be anything other than loving and supportive to any child born into their family.[12]

3. 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:

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[12] HC Deb, 19 May 2008, c107.

> 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.

As introduced, clause 14(2) of the Bill would have omitted from Section 13(5) of the HFE Act "including the need of that child for a father". This was amended by the Government during the Lords 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". This remains a contentious clause that has attracted interest from lobbying groups calling for its removal. Equally organisations calling for equal rights for same sex couples have welcomed the progress of the Bill.

Ian Duncan Smith tabled amendments to include the need of a child for a "father or male role model". He argued that research suggested closer contact with fathers led a greater sense of self worth and less contact with police among adolescents:

> Since 1990 there has been a huge amount of research on the effect of absent fathers, demonstrating an increasing understanding of the importance of the role that fathers play in the home. That is not to suggest that if a family breaks up and the father leaves, that is simply bad for the children: research that we published recently, which was drawn from more than 3,000 evidence sessions, showed that the effect on those broken families is remarkable—75 per cent. of the children are more likely to fail at school, 70 per cent. are more likely to succumb to drug addiction, 50 per cent. are more likely to have serious alcohol problems, and 35 per cent. are more likely to experience some form of unemployment or welfare dependency.
>
> The research highlights the fact that fathers bring something more profound to the parenting process, which has for too long been taken for granted. In some cases people determined that it should not be discussed. One set of evidence published as recently as 2007 by the Joseph Rowntree Foundation states:
>
> "Maternal 'inputs' are not consistently correlated with indices of their children's development once they enter secondary school, whereas paternal 'inputs' *are* so correlated. Indeed, there is an indication that teenagers' sense of self-worth is predicted by the quality of their play with their fathers some 13 years earlier."
>
> The report goes on to say that that,
>
> "has demonstrated links between parental reports of father's involvement at the age of seven and lower levels of later police contact as reported by the mothers". Obviously, that makes the strong and profound point that the effect of fathers on both sexes during the teenage years is important.
>
> Something of which I had not been aware came from the research that we have conducted in the past two and a half years, and I should like to put it before the Committee. It was simply this: the effect that absent fathers also have on young girls. That issue is often forgotten. We always hear of the effect of a father's absence on young boys in respect of the whole issue of role modelling and giving them a stable beginning. However, in Britain we have some of the highest levels of under-age sexual activity, particularly among young girls, and there is very

> strong evidence to suggest that the effect of an absent father is to distort that further. That is because young girls more often learn empathetic and non-conditional love—something important and profound—from their fathers. They learn that it is possible to have a relationship that does not necessarily involve sex. We all know about the pressures that a young girl is under from young boys at such a time, and her relationships may have to countenance sex at an early stage. From most of the studies, it is clear that the absence of a base from which to understand how far such relationships need to go has a huge effect on such daughters.
>
> The studies that we have been considering show consistently that such girls lose out in a way that we have not understood or even talked about enough. We know all about how sons need stable father figures who give them decent modelling, such as going out to work and having a creative relationship with the mother; however, the absence of a father is as significant for a daughter as for a son. The evidence on young daughters is also absolutely critical.[13]

A case against this was presented by Emily Thornberry and others who argued that to provide for the requirement for a father would discriminate against lesbian couples seeking IVF treatment:

> My point is this. Frequently asked questions and the answer are one thing, and an overt piece of discrimination is something else. If there is a lack of clarity in the current law, we have an opportunity to sort it out today. If we were to confirm the need for a father, to add the need for a mother or to move away from the carefully thought out wording proposed by the Government, there would be increased confusion—or, worse, no clear law at all. Many hospitals would have eligibility criteria for IVF treatment as explicit as that published in Birmingham, so we would then have to wrestle with the Human Rights Act.[14]

On division no amendments were accepted and this part of the Bill remains unaltered.

4. 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 Fertilisation and Embryology Act 1990*[15] which the Bill is to amend. During the Committee of the whole House the legislation was not changed.

a. Time limits

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 time limit of 24 weeks for grounds C and D (see below). Grounds A, B and E are now

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13 HC Deb, 20 May 2008 c166-7
14 HC Deb, 20 May 2008 c176
15 *Human Fertilisation and Embryology Act 1990* section 37

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.[16]

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

A range of amendments were tabled in Committee of the whole House to reduce the time limit for abortions under grounds C and D from between the 12th to the 20th week. Edward Leigh set out his reasoning behind the greatest reduction to 12 weeks:

> There is rightly much talk in the House about human rights and the rights of the vulnerable. In my personal view, there is just one, overwhelming, fundamental human right: the right to life. I must confess that my views have changed over the years. If I am to be honest with myself, I have to take an entirely consistent position. If a vote were to be held on capital punishment, I would vote against it. That is why I voted against all the recent wars, and why I am voting as I am on the Bill. I believe that one can take only a consistent position based on humanity, with all its faults and disabilities. That is where I stand; I do not know any other way. I hope that the House will forgive those of us who take that position.[17]

Further evidence was presented by Mark Pritchard who argued for a reduction to 16 weeks:

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16 British Pregnancy Advisory Service (bpas): Abortion webpage [on 2 May 2008]
17 20 May 2008, c225

> Why 16 weeks? Scientific evidence increasingly suggests that unborn children feel pain at 16 weeks. That is not simply a stress response; it is a physiological response, perhaps not the same as in a fully grown adult, but a physical and even emotional response beyond the norms of passive reflex. Pain is felt, which is why specialist, gifted surgeons who perform surgery on babies in the womb use anaesthetic. Now, 4D imaging reveals that 16-week-old unborn babies are very much alive and kicking, although their limbs are too small to be felt by the mothers. Those who have had children know that they are likely to feel kicking at around 17 weeks in the case of a second baby and 19 weeks in the case of a first baby. However, just because the mother does not feel kicking, it does not mean that there is no leg kicking.
>
> Sixteen-week-old unborn babies are very small human beings, but they have many of the faculties of newborn babies. I will probably get told off for doing this, but I have a picture of a 16-week-old unborn baby. It speaks for itself.[18]

The Bill remains unchanged in this area.

b. Informed Consent

A new clause was tabled that would require counselling and information, beyond that which is already given, on foetal development and the risks associated with abortion, is provided to anyone seeking an abortion.

A further new clause was tabled to require that if tests revealed a child were to be born with a physical or mental abnormality then the parents should be supplied with information on, life expectancy, expected functional development and treatment options for the child.

These amendments were not agreed to.

B. Public Bill Committee

The remainder of the Bill was committed to a Public Bill Committee which sat on eight occasions; these are listed in Appendix II. The membership of the Committee is listed in Appendix I.

72 Government amendments were agreed to but no new clauses were included by the Government. Most of these amendments were consequential and many relate to a rewording of the terminology used to describe classes of people within the Bill.[19]

No opposition amendments were successful and no opposition new clauses were introduced.

The Committee received two pieces of evidence:

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[18] HC Deb, 20 May 2008 c235.

[19] "P" replaced the term "patient" and "C" replaced the term "child donor" in many parts of the Bill.

Memorandum submitted by Jane Majkawski (HF 01)
Memorandum submitted by Dr E Allan (HF 2)

The Bill was not changed greatly by the Committee. Most significantly Government amendments on the use and storage of cells from those lacking capacity (either as children or adults) or where the donor can no longer be identified or has died were agreed to.

1. Meaning of Embryo (Clause 1)

Clause 1 of the bill provides a definition of embryos. It does not provide a definition of fertilisation and concerns were raised that the licensing regime established by the bill may not effectively cover all cell types and processes associated with embryos. The Minster was confident that the Human Fertilisation and Embryology Authority could make decisions using the terminology set out in the Bill.[20]

2. Stem Cell Derived Gametes (Clause 3)

Clause 3 set out those embryos which are permitted to be transplanted into a woman.

One potential benefit of stem cell research could be the artificial creation of sperm or eggs using a patients own DNA. These could be used in situations where an individual is unable to produce viable gametes and unable to have children. Evan Harris raised the point in relation to cancer patients who may become infertile during treatment.

The Minister set out that the Bill provided an effective mechanism to research the potential of stem cell derived gametes and that further Parliamentary scrutiny would be required in the future if the technology were to be made available:

> The Government's position is that, if research into artificial gametes demonstrates that they might effectively be used in treatment, this should of course be considered. However, our current view is that there is too little research into how these cells might be derived, and into the safety of such techniques, to be able to make an informed judgment about their use. The application of this technology would be highly significant. It would mean a baby being born having been created from cells other than eggs and sperm, and it is my view that it would not be appropriate to allow such a significant development without proper consultation and parliamentary scrutiny.[21]

3. Consent (Schedule 3)

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.

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[20] PBC, 3 June 2008, c9.
[21] PBC, 3 June 2008, c45

The Bill updates the HFE Act to take account of the fact that an embryo can now be created without fertilising an egg. 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.

a. Posthumous Donation of Gametes

Two recent cases have highlighted the possibility of using sperm posthumously taken from a man to be used in fertility treatment when consent is unclear. These were set out by Evan Harris in the Committee:

> This case—I am not going to dwell on it at length, because it is the law that we want to discuss today—relates to a lady, aged 42, whose husband died suddenly in June last year. He was 30 at the time, and the cause of his death was unclear, despite a post mortem. They already had one child, but there were some questions about the woman's fertility and they wished to have a further child. They went to see a consultant obstetrician and gynaecologist to discuss whether the particular problem that she had might affect her natural conception. Unfortunately, and tragically, the husband died the week following that.
>
> Sperm was then taken from the man posthumously and stored. The legality of that act was confirmed at the first stage, before it was carried out, by an urgent out-of-hours court hearing in the High Court by telephone conference. The Human Fertilisation and Embryology Authority was not represented, which might be relevant to what happened subsequently.
>
> The proposal then was for the sperm to be used in treatment, either in this country or abroad. There are difficulties with the existing law, as set out by the Human Fertilisation and Embryology Act 1990, and I do not think that the problems that this woman is encountering under that Act will be made any easier under the proposals in the Bill. The Government are pretty clear that they take the issue of consent very seriously. The term used is "effective consent", and there are certain criteria for that. I do not think that anyone could generally describe the proposals in the Bill as a watering down of what existed in 1990.
>
> In the Diane Blood case, which is the only legal precedent for this, sperm was taken from Mr. Blood, albeit not posthumously, but while he was in a coma. I happen to think that that case raises greater issues around the removal of sperm, because there is a potential for assault in such a case, when someone is not dead. It is not possible to assault a dead body, even though there are obvious sensitivities surrounding that.
>
> In the Diane Blood case, the sperm was taken and stored, as I understand it, without a court hearing, and then the question was whether that could be used for treatment without the effective consent. Under the 1990 Act, effective consent for the storage of sperm requires it to be in writing. Effective consent for the use of the sperm in treatment is also required in writing. It must be extant and not withdrawn prior to use. That clearly did not apply in the case of Diane Blood, although she asserted strongly that she and her late husband had had a discussion and that had said that he would have wanted her to have a child after

> his death. There was certainly no doubt that they wanted to have children together.[22]
>
> In that case, the HFEA would not allow the sperm to be used in treatment in this country and would not allow export, although I understand that it has the discretion to do so. Following a court hearing, the court directed the HFEA to reconsider its decision, taking into account European law. The HFEA, whether or not it did so, decided in the end to allow Diane Blood to export the sperm to a European country—I believe that it was Belgium—although I understand that that was because it had run out of money to fight the case and had been given a steer from the Government, whether appropriately or inappropriately, not to pursue the matter much further.

An unsuccessful amendment by Dr Harris would provide that the High Court could make a decision on the use of gametes for which consent had not been given for storage and use after death.

The Minister recognised that the outcome of a current legal case may address the complexity of this problem and added that the Government is satisfied that the HFEA is the appropriate authority to decide on the use of gametes for treatment purposes.

b. Research Using Stored Cells

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 in some cases for research.

Medical research establishments have built up repositories of cells from patients with rare conditions. These are of particular importance because new therapeutic cloning techniques mean that embryos can be created from these cells which 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.

A Government amendment was passed to allow an exception to the requirement for consent. The Minister explained how this exception would work:

> With regard to stored cells, the Government amendments apply only to cells taken and stored before the commencement of the Bill's provisions. The exception applies only if the HFEA is satisfied that the cells are anonymous and that the donor cannot be identified, or that the licence holder cannot reasonably trace the donor.
>
> If the researcher can identify and trace the donor, unless the donor consents themselves, the cells cannot be used. If the person identifies the donor, and they are found to be deceased, consent would be required from a person such as a close relative, as set out in the hierarchy model found in the Human Tissue Act

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[22] PBC, 5 June 2008, c76.

> 2004. Before the cells can be used, the HFEA must be satisfied that scientific research would be adversely affected to a significant extent if the only cells that could be used were cells for which consent had been obtained.
>
> The amendments reflect the fact that rare or well-researched samples are a valuable asset for better understanding and treating serious diseases. We have weighed the burden of being unable to use those cells against the rights of the person who originally donated them, and we believe that we have struck the right balance with the amendments.
>
> On consent for the use of cells from children, the amendments apply when those children would never be able to give their consent because of age or lack of capacity. This is the case with children affected by certain aggressive forms of diseases such as muscular dystrophy, Batten disease and spinal muscular atrophy. To that end, the amendments propose that children with such conditions who are too young to consent, or who lack capacity, should be excluded from the requirement for effective consent, if a person with parental responsibility gives consent. This exception is subject to strict safeguards that ensure that a child's cells cannot be used unless the HFEA is satisfied that the child suffers from a serious medical condition, that the research is intended to increase knowledge about the condition or its treatment, and that there are reasonable grounds for believing that research of comparable effectiveness could not be carried out using the cells of a person who could give their own consent.[23]

c. Consents for Children and Others Lacking Capacity

Further Government amendments were agreed to that would clarify the consent process for the use of cells taken from children and adults lacking capacity. Debate in the Committee displayed support for these from all sides. The Minister described how these would work:

> On consent for the use of cells from children, the amendments apply when those children would never be able to give their consent because of age or lack of capacity. This is the case with children affected by certain aggressive forms of diseases such as muscular dystrophy, Batten disease and spinal muscular atrophy. To that end, the amendments propose that children with such conditions who are too young to consent, or who lack capacity, should be excluded from the requirement for effective consent, if a person with parental responsibility gives consent. This exception is subject to strict safeguards that ensure that a child's cells cannot be used unless the HFEA is satisfied that the child suffers from a serious medical condition, that the research is intended to increase knowledge about the condition or its treatment, and that there are reasonable grounds for believing that research of comparable effectiveness could not be carried out using the cells of a person who could give their own consent.
>
> I turn to consent for the use of cells from adults who lack capacity. Following further consideration of the exception relating to cells from children, it became clear that it was also desirable to make provision to enable the use of cells from an adult who lacked capacity in very limited circumstances. That would be to address situations when, for example, rare genetic conditions led to the sudden

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[23] PBC, 5 June 2008, c98

> onset of lifelong incapacity. Following the precedent of the Mental Capacity Act 2005, the Government amendments propose that in such cases, the researcher would need to approach the carer of the individual and consult them about the views or the wishes of the person involved.
>
> Again, this exception is subject to a number of stringent safeguards. The HFEA must be satisfied—at the time the adult lacks capacity and is unlikely to have capacity again—that the adult suffers from a serious medical condition, that the proposed research is intended to increase knowledge about the condition or its treatment, that there is no evidence that the adult would have refused to participate and, most importantly, that there are reasonable grounds for believing that research of comparable effectiveness could not be carried out using the cells of a person who could have given their own consent.
>
> In all cases, it will be for the researcher to provide evidence that satisfies the HFEA that all conditions have been met before a licence to undertake the research may be given. The exemptions are rooted in exceptional circumstances. The potential for benefits to the sufferers of serious conditions must be too great to overlook, and any research that can be undertaken in the hope of better treating or curing those conditions must be allowed to continue.[24]

d. Disclosure of Information (Clause 25)

Government amendments were agreed to that would increase scope for the disclosure of information between medical practitioners and those involved in IVF treatment. Most importantly the amendments provide that information that could identify an individual could now be disclosed. The HFE Act set out that identifying information could not be disclosed for the protection of donors and children, even when consent had been given. The amended Bill would allow this information to be made available if consented to or on certain health grounds. These amendments were welcomed by all parties.

4. Fees (Clauses 6 and 27)

Two divisions were held on amendments to regulate the charges made by the Human Fertilisation and Embryology Authority.

a. Fees for Advice

The first involved an amendment tabled by Mark Simmonds that would remove the right of the Authority to charge a fee for advice as provided for in clause 6 of the Bill. Mr Simmonds asked this new provision was required. The Minister replied:

> The provision is intended to allow the HFEA to recover costs that it has incurred in providing specialist advice. It was considered appropriate to make the power discretionary, which enables the HFEA to consider whether a charge is necessary. It is not about income generation. It is a discretionary levy that will be used only when appropriate, such as if a clinic wants to consider what systems it

[24] PBC, 5 June 2008, c98

> needs to put in place to comply with a European directive. It will be provided for within the national health service if we are required to move the entire service to comply with a particular European directive, or if a restructuring of the service is necessary. The amount of work generated for the HFEA by such a request could go way beyond the usual requests suggested by the hon. Members for Boston and Skegness and for Salisbury.[25]

The Committee divided (Ayes 7, Noes 8) and the clause was passed without amendment.

b. Fees for IVF Treatment (Clause 27)

The Bill would allow the HFEA to fix fees for IVF licences with the approval of the Secretary of State. A second set of amendments would require that any fees could only be used to cover costs incurred in licensing and would require that these fees had to be agreed in Parliament. The Committee divided against the amendments (Ayes 5, Noes 11).

5. Surrogacy and Birth Certificates (Clause 35)

The law on surrogacy is set out in the *Surrogacy Arrangement Act 1985*, and the HFE Act. Currently the husband of a surrogate mother will generally be treated as the father of the child. The Bill would extend this provision to civil partners so that the partner of a surrogate mother will also be treated as the parent of a child. This is to reflect the fact that civil partnerships have the same legal status as marriage.

To provide the commissioning parents with quicker parental rights over a surrogate child Evan Harris tabled an amendment that would enable the commissioning father to be regarded as the child's parent.

The amendment was withdrawn but the Minister reminded the Committee of the Government's intention to review the existing surrogacy regulations.[26]

A range of additional opposition amendments were tabled to take account of contingencies that may be necessary to accommodate the permutations of possible parents in cases of surrogacy. These took account of same sex couples, possible donors and single parent options for adoption. None of these were agreed to.

6. Parliamentary Committee on Bioethics

The Joint Committee on the Human Tissue and Embryos (Draft) Bill looked at the issue of bioethics regulation in the UK and examined whether it is appropriate for ethical

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[25] PBC, 3 June 2008, c56.
[26] PBC, 10 June 2008, c215.

decisions to be taken by the regulator (currently the HFEA); or whether ethical decisions should be taken by an outside body.[27]

Brian Iddon tabled a new clause to establish a committee of both Houses to deal with bioethics issues. The clause received support from the Committee but was considered by the Minister to be a matter beyond the scope of the Bill and rather something to be decided by Parliament through the traditional process.[28]

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

[28] PBC, 12 June, 2008, c293.

Appendix I Members of the Public Bill Committee

Chairmen: Mr. Roger Gale, Mr. Jim Hood

Clarke, Mr. Tom *(Coatbridge, Chryston and Bellshill)* (Lab)
Gibson, Dr. Ian *(Norwich, North)* (Lab)
Harris, Dr. Evan *(Oxford, West and Abingdon)* (LD)
Iddon, Dr. Brian *(Bolton, South-East)* (Lab)
Jones, Helen *(Warrington, North)* (Lab)
Key, Robert *(Salisbury)* (Con)
McCabe, Steve *(Lord Commissioner of Her Majesty's Treasury)*
McCafferty, Chris *(Calder Valley)* (Lab)
Moffatt, Laura *(Crawley)* (Lab)
Morgan, Julie *(Cardiff, North)* (Lab)
Penning, Mike *(Hemel Hempstead)* (Con)
Primarolo, Dawn *(Minister of State, Department of Health)*
Pugh, Dr. John *(Southport)* (LD)
Simmonds, Mark *(Boston and Skegness)* (Con)
Streeter, Mr. Gary *(South-West Devon)* (Con)
Turner, Dr. Desmond *(Brighton, Kemptown)* (Lab)
Wright, Jeremy *(Rugby and Kenilworth)* (Con)

Hannah Weston, Celia Blacklock, *Committee Clerks*

Appendix II Stages of the Bill

Lords Stages

- 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

Commons Stages

- First Reading: 5 February 2008 [HL Bill 70]
- Second Reading: 12 May 2008
- Committee of the Whole House:
  - 1st day: 19 May 2008
  - 2nd day: 20 May 2008
- Public Bill Committee:
  - 1st session: 3 June 2008 (am)
  - 2nd session: 3 June 2008 (pm)
  - 3rd session: 5 June 2008 (am)
  - 4th session: 5 June 2008 (pm)
  - 5th session: 10 June 2008 (am)
  - 6th session: 10 June 2008 (pm)
  - 7th session: 12 June 2008 (am)
  - 8th session: 12 June 2008 (pm)

Additional materials including Amendment Papers and Proceedings are available on the Parliamentary Public Bill Page.