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

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
October 2007

Cm 7209

£5.00

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Foreword

On 17 May 2007, the Government published draft legislation to revise and update the Human Fertilisation and Embryology Act 1990. This was set out in the Human Tissue and Embryos (Draft) Bill.[1]

The provisions of the draft Bill were based on proposals published in a December 2006 White Paper,[2] which followed an extensive review of the law and a public consultation. The Government undertook the review in light of the development of new procedures and technologies in assisted reproduction, possible changes in public attitudes on complex ethical issues and the need to ensure that regulation remained fit for purpose in the 21st century.

Separately, the Department of Health had undertaken a review of its arm's length bodies in 2004.[3] This led to the proposal in the draft Bill to replace the Human Fertilisation and Embryology Authority and the Human Tissue Authority with a single body – the Regulatory Authority for Tissue and Embryos.

In the White Paper, the Government set out its principal aims for revised legislation as follows:

- To ensure that legitimate medical and scientific applications of human reproductive technologies can continue to flourish.
- To promote public confidence in the development and use of human reproductive technologies through effective regulatory controls applicable to them.
- To secure that regulatory controls accord with better regulation principles and encourage best regulatory practice.

1 Cm 7087.
2 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, Cm 6989, December 2006.
3 *Reconfiguring the Department of Health's Arm's Length Bodies*, July 2004.

The Government therefore welcomed the establishment of a joint committee of both Houses of Parliament to undertake pre-legislative scrutiny of the draft Bill. The subsequent scrutiny report was published on 1 August 2007.[4] The Government is grateful to the Joint Committee for its analysis and recommendations, which build on public and parliamentary debate over the past few years.

This paper sets out the Government's response to all of the Joint Committee's 31 recommendations. Recommendations addressing similar issues have been grouped together where appropriate, so they do not always appear in chronological order.

4 HL Paper 169-I and HC Paper 630-I. Written and oral evidence published as Volume II.

Response to the Committee's conclusions and recommendations

Public opinion and public understanding

Recommendation 1

We recommend that the Government should commission independent public policy research into general public opinion on issues arising from scientific and ethical developments in this field and the wider field of bioethics, either through the Research Councils, for example, the ESRC and AHRC, or other appropriate organisations. (Paragraph 23[5])

Recommendation 2

We recommend that the Government and the regulator should take a more active approach to fulfilling their duty to improve and inform public understanding of the issues in this area. (Paragraph 26)

1. The Government agrees with the Committee that full public debate on complex scientific and ethical issues is vital to ensure sound policy-making.

2. An example of this is the Government's Sciencewise programme, which aims to help policy-makers find out the public's views on emerging areas of science and technology in order to take account of them when making national policy decisions. The programme stems from the Government's aim to build a society in which the public, the science community and policy-makers feel comfortable in handling issues raised by science and technology, and feel a joint sense of purpose in ensuring that the full benefits of science and technology are realised.

3. Sciencewise is currently funding a public dialogue programme to gain insight into public attitudes towards stem cell research. The Biotechnology and Biological Sciences Research Council (BBSRC) and the Medical Research Council (MRC) will explore public concerns, views and attitudes, and provide opportunities for scientists to discuss with the public the challenges that researchers face and the potential benefits.

5 Paragraph numbers refer to where each recommendation occurs in the Joint Committee's report, as published.

4. Sciencewise provided advice to the Human Fertilisation and Embryology Authority (HFEA) about the format of its consultation on the creation of human-animal hybrids for research. This support of the consultation helped ensure that it was effective in gauging public opinion and attitudes, as well as making sure that the consultation was run in line with the Government's guiding principles for public dialogue on science and technology.

5. The Department of Health (DH) has also funded forums for public debate, including online discussion, in connection with the review of the Human Fertilisation and Embryology Act (1990).

6. DH will continue to work with the appropriate regulators and stakeholders on issues of science and bioethics to consult and inform the wider public, and to look for the most effective ways of doing this.

Legislative and ethical framework

Ethics outside the regulatory framework

Recommendation 3

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. (Paragraph 48)

7. 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'.[6] 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.

The regulatory architecture: getting the balance right

Recommendation 4

We recommend that the draft Bill should be amended to provide a clear framework based on the principle of devolved regulation. Legislation should devolve regulatory authority and decision making to the regulators, who in turn should be given the power in legislation to define areas of 'exemption' within their regulatory remit. This would provide a framework of 'permitted regulation' and give greater freedom and authority to the regulator and clinicians except where there is good reason to do otherwise. The draft Bill should also provide a statutory power for the Secretary of State to make regulations subject to affirmative resolution and only on the application of the regulator, to make provisions where necessary for the remit or authority of the regulator. We also note the criteria used by the Medical Research Council to

6 The Joint Committee's report, paragraph 48.

judge applications for research grants and we recommend that these could be built on to provide legislative parameters for research set out in the draft Bill. If this recommendation is accepted, it follows that the appointment of members of the regulatory body would require a balance of ethical, scientific, legal and medical expertise; and the Chair should be a proven leader of the highest calibre and appropriately remunerated. (Paragraph 56)

Recommendation 6

In accordance with our recommendation about a framework of permissive regulations, we recommend that the draft Bill should be amended to give the regulator statutory power to define areas of exemption from the current regulatory remit where appropriate. We also support calls for a lighter touch and, where it would be appropriate, we urge the regulators to investigate ways in which the unnecessary duplication of regulation can be eliminated. (Paragraph 105)

8. For the reasons set out below, the Government does not agree that a framework of devolved regulation as described in the scrutiny committee's report is appropriate. Most importantly we believe that such a framework would introduce a lack of accountability.

9. The Government believes that in making these two recommendations the Committee had two particular goals in mind: lighter touch regulation, or even de-regulation, of 'standard *in vitro* fertilisation (IVF)'; and allowing the HFEA to have increased flexibility, specifically with regard to regulating inter-species embryos. The Committee states: 'We recognise that there is a balance to be struck between legal certainty and flexibility', and 'we favour a more flexible approach within clearly defined parameters.' The report goes on to say that 'in taking this permissive view, we recognise that this approach will be open to broader interpretation and, perhaps, more frequent challenges in the courts.'[7]

10. The EU Tissues and Cells Directive[8] sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of all human tissue and cells intended for human application. It came fully into force in the UK on 5 July 2007 and requires that all assisted conception treatment services involving gametes and embryos are regulated and meet certain standards as set out by the Directive. Therefore, it would not be possible to exclude 'standard IVF' from regulation.

11. The Government believes that bringing all human-animal research within the HFEA's remit and giving the HFEA the power to make exemptions from regulation would cause uncertainty about the scope of regulation. It would require the HFEA to make decisions about animal research involving human genetic material that are currently within the Home Office's regulatory remit. The Government believes that giving more regulatory flexibility in this way would be confusing and open up the HFEA to increased litigation and judicial review.

7 The Joint Committee's report, paragraph 55.
8 Directive 2004/23/EC.

12. The Government does, however, propose that the HFEA is given more flexibility to make licensing decisions with respect to a list of inter-species embryos that is defined in the Bill. The Government will give the HFEA the remit to license research in this area, subject to the usual requirements of the research being necessary or desirable.

13. The Government supports the move towards lighter touch regulation, as indicated by a clause in the Bill that stipulates that the HFEA must carry out its functions effectively, efficiently and economically and with regard to the principles of best regulatory practice.

The Regulatory Authority for Tissue and Embryos

Recommendation 5

We have found the evidence against establishing RATE overwhelming and convincing and we recommend that the Government abandons the proposals in Part 1 of the draft Bill. We consider that the regulatory oversight provided by the HFEA and the HTA is better than the oversight that could be provided by RATE and we recommend that the HFEA and the HTA (as well as the MHRA) should be retained as separate authorities. However we note the lack of research undertaken as to the workings of the current regulatory structure, and improvements that could be made. We recognise that greater savings, consistency, efficiency and co-operation might be achieved both within and between the two organisations. We recommend that the Government, in consultation with the HFEA, HTA and their stakeholders, look at ways to achieve such improvements. (Paragraph 92)

14. The proposal to establish the Regulatory Authority for Tissue and Embryos (RATE) arose from DH's review of its arm's length bodies[9] 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.

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.

9 *Reconfiguring the Department of Health's Arm's Length Bodies*, July 2004.

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.

Reform of the Human Tissue Act 2004

Recommendation 7

In consultation with the Human Tissue Authority and its stakeholders, we recommend that the Government use the opportunity presented by the draft Bill to make necessary amendments to the Human Tissue Act 2004. (Paragraph 114)

18. The Government notes the evidence provided to the Committee and recognises the Committee's and stakeholders' concerns on this matter. However, we remain unconvinced that it constitutes a compelling mandate for making significant change, at this time, to legislation that has so recently been the subject of wide-ranging consultation and public and Parliamentary debate.

19. The Government is aware that the list of persons in a qualifying relationship, listed in the Human Tissue Act 2004,[10] is causing some practical difficulties because of the omission of some close relationships such as aunts and uncles (as outlined by the Committee),[11] and we will work with stakeholders to resolve this. The 2004 Act contains a provision to allow the Secretary of State to amend this list by order, if necessary.[12]

Research licence fees

Recommendation 8

We recommend that Research Council grants should include the cost of research licences. (Paragraph 123)

20. The Government believes that it is a matter for the funding bodies themselves to decide whether grants they award to centres to conduct embryo research should include the cost of the centre's research licence fees.

Treatment fees

Recommendation 9

We are concerned by some of the comments we have heard about fees and unproven treatments and we recommend that the draft Bill is amended to meet the HFEA's suggestion that assisted conception clinics should provide patients with fully costed treatment plans. We recommend that the HFEA works with the Royal Colleges and other appropriate professional bodies to protect patients from any risk of exploitation. (Paragraph 127)

10 Section 27(4).
11 The Joint Committee's report, paragraph 108.
12 Section 27(9).

21. The Government recognises the Committee's concerns and agrees that there is a need for patients to be better informed about what they are paying for when receiving assisted conception treatment. DH 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 information to patients of the costs of their treatment in advance.

National Institute for Health and Clinical Excellence (NICE) guidelines

Recommendation 10

We recommend that the Government takes steps to ensure that Primary Care Trusts and Foundation Trusts implement NICE guidance which sets out minimum levels of treatment. (Paragraph 129)

22. Although this issue is not a matter for the legislation, the Government welcomes the Committee's recommendation. The Government's recognition of the importance of NHS provision of IVF was demonstrated by our instigation of the NICE clinical guideline on the assessment and treatment of people with fertility problems.[13]

23. DH is currently funding a three-year programme of work being carried out by the leading patient organisation, Infertility Network UK, that aims to reduce inequalities in the provision of IVF and to implement the NICE clinical guideline on fertility. The Government has also announced the monitoring of IVF provision across the country.

Amendments of the Human Fertilisation and Embryology Act 1990

Definitions in clauses 14 and 15

Recommendation 11

We support the definitions in clauses 14 and 15 of the draft Bill and recommend that the detail in relation to how these definitions will be applied be left to the regulator. (Paragraph 138)

24. The Government welcomes the Committee's support for the definitions set out in clauses 14 and 15 of the draft Bill. The intention is that it will be left for the regulator to decide how these definitions will be applied in practice. As mentioned in the Committee's report, this approach is supported by the HFEA who said that 'it is essential that the definitions in the Act enable the regulator to regulate tissues with reproductive capacities whichever way they are created or derived.'[14]

13 http://guidance.nice.org.uk/CG11
14 The Joint Committee's report, paragraph 138.

Inter-species embryos

Recommendation 12

We can see no clear reason why certain categories of inter-species embryo should be permitted under licence and 'true' hybrids proscribed. We recommend that the HFEA should be left to judge which entities may be created, kept and used for research purposes under licence. (Paragraph 161)

Recommendation 14

If Parliament supports the provisions regulating inter-species embryo research, we would make the following further recommendation. In line with our recommendation supporting an architecture of 'permitted regulation', we recommend that the Government should revisit its approach to the definition of inter-species embryos in the draft Bill with a view to providing a general definition along the lines of the approach set out in paragraph 176, with authority given to the regulator to interpret and apply that definition to individual research applications, based on the principles set out in legislation; statutory authority to exempt areas of research from the licensing provisions where appropriate; and with a statutory power for the Secretary of State to make regulations, only on the application of the regulator, to make provisions in respect of a particular research application. (Paragraph 178)

25. The Government recognises the importance of maintaining public trust in the regulation of embryo research. Our position on research using inter-species embryos has developed with particular regard to this principle. We have balanced factors such as the need for legitimate research to have appropriate flexibility; the potential for understanding and treating serious disease; strong views expressed by members of the public; and the wide range of evidence gathered.

26. The 1990 Act provides a legislative framework for the regulation of research projects involving human embryos, in accordance with legal limits. One of those limits is a prohibition on the mixing of human and animal gametes, which could (in theory) result in the creation of 'true' hybrid embryos.[15] Otherwise, the current legislation does not explicitly mention any other form of inter-species embryo, and the Government sought to address this issue in its review of the law.

27. In the 2006 White Paper, following developments in the potential creation of inter-species embryos for research, the Government stated that revised legislation would clarify the extent to which regulation would apply to embryos containing both human and animal material.[16] The proposal was that such embryos would be defined and prohibited in legislation, but this would be subject to a regulation-making power for Parliament to enable the regulator to license such research.

15 With the exception of the sperm penetration test using a hamster egg. This test is to assess the quality of human sperm and the product of the test must be destroyed no later than the two-cell stage.

16 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, December 2006, Cm 6989, paragraph 2.85.

28. Following publication of the White Paper, the House of Commons Science and Technology Committee conducted an inquiry into the Government proposals on inter-species embryos. In particular, the Committee focused on the creation of 'cytoplasmic hybrid' embryos, which would involve replacing the nucleus of an animal egg with a human cell or cell nucleus to create an embryo. The Committee's report concluded that the creation of inter-species embryos should be allowed for research under the aegis of the regulator, without the need for further (secondary) legislation as proposed.[17]

29. The Government accepted in principle the recommendation of the Science and Technology Committee in relation to the majority of the inter-species embryos covered by the draft Bill. This did not, however, include 'true' hybrids created from mixing human and animal gametes, as there seemed to be a less compelling case for such creations, and the Government believed that a regulation-making power provided sufficient flexibility to respond to future developments.

30. The Joint Committee's report has very helpfully moved this debate forward. The Committee has recommended greater scope of discretion for the regulator, and also that the creation of 'true' hybrid embryos should be within the regulator's licensing remit.

31. The Government will revise the Bill in order to put this proposal to Parliament for wider debate. Acceptance of this proposal would devolve decision-making to the regulator to permit or refuse licences in relation to all inter-species embryos covered by the draft Bill, subject to the statutory requirements and limits of the 1990 Act.

32. While the Government shares the desire for clear terms discussed in the report, the 'working definition' cited would not be compatible with the Government's proposed model of regulation, for the reasons discussed in response to recommendations 4 and 6. The definition would also encompass a number of important research projects which are regulated under legislation governing scientific procedures involving animals, overseen by the Home Office,[18] rather than under legislation regulating human embryos.

33. DH has discussed the available approaches with representatives from a number of professional bodies, including the Academy of Medical Sciences, the Royal Society, the MRC and the Wellcome Trust. On balance the Government believes that the current approach (which in part follows the precedent set by Canadian legislation[19]) remains appropriate and workable.

17 *Government Proposals for the Regulation of Hybrid and Chimera Embryos*, House of Commons Science and Technology Committee, March 2007, HC 272-I, Section 3.
18 The Animal (Scientific Procedures) Act 1986.
19 Assisted Human Reproduction Act (2004, c.2), Parliament of Canada.

34. The Bill will now bring the following inter-species embryos within the scope of the regulator, where licences may permit their creation subject to the requirement that the project is necessary or desirable for the purposes described in legislation:

    - 'True' hybrids – embryos created by the mixing of human and animal gametes.
    - 'Cytoplasmic hybrid' embryos – embryos created by the insertion of a human nucleus into an enucleated animal egg.
    - Human transgenic embryos – human embryos modified by the addition of animal DNA.
    - Human-animal chimera embryos – embryos created by the addition of animal cells to a human embryo.

35. Additionally, clause 4A(5)(e) will be dropped from the revised Bill, and replaced with a regulation-making power to extend the definition of inter-species embryos. This will provide future flexibility to ensure that the law keeps pace with technological developments.

Recommendation 13

We note that, when what is now the 1990 Act was before Parliament, the issue of embryo research was put to a free vote. We consider that the creation and use of inter-species embryos for research purposes is a comparable issue, and we recommend that the issue is put to a free vote in both Houses. (Paragraph 177)

36. The Government notes the Committee's recommendation that the creation and use of inter-species embryos for research purposes is put to a free vote in both Houses. Free votes have historically been a feature of Parliamentary debates in this field, and this would ultimately be a matter for the Government and the opposition parties to decide upon at the appropriate time.

Prohibitions in respect of embryos and mitochondrial DNA from two women

Recommendation 15

We recommend that the Explanatory Notes to the draft Bill be revised to make clear and explicit that a "permitted embryo" cannot be created from the genetic material of two women alone and that, in the case of mitochondrial donation, the child will essentially have only two parents, one male and one female. We also recommend that the Government gives an ongoing commitment that, if the technology became available to create an embryo only from the genetic material of two women without the need for fertilisation by a sperm, any question of whether such an embryo should be allowed to be inserted into a woman should be a matter for Parliament to decide. (Paragraph 186)

Recommendation 16

We recommend that the Explanatory Notes to the draft Bill be revised to make clear and explicit that a cloned embryo cannot be a "permitted embryo" and we also recommend that the Government gives an ongoing commitment that any question of amending these provisions should be a matter for Parliament to decide. (Paragraph 188)

37. The Government remains committed to a ban on human reproductive cloning, and this position is not altered by any provision of the draft Bill.

38. The provisions of the draft Bill allow only 'permitted embryos' as defined in the Bill to be placed in a woman. A permitted embryo is created by the fertilisation of a 'permitted egg' (one which has been produced by or extracted from the ovaries of a woman) by a 'permitted sperm' (produced by or extracted from the testes of a man), and where no nuclear or mitochondrial DNA of the sperm, egg or embryo has been altered. This would exclude any embryos created by 'cloning' another individual.

39. The draft Bill includes a regulation-making power that allows (subject to the affirmative process) embryos that have undergone a specific process to avoid transmission of mitochondrial disease, to be 'permitted embryos'. It is intended that such embryos would have nuclear genetic material from one male and one female, but mitochondrial genetic material from an egg donor. The Government will amend the explanatory notes to make this clear.

40. As outlined in the December 2006 White Paper,[20] any other changes to the scope of the meaning of 'permitted embryo' would be a matter for future primary legislation.

Tissue typing and 'saviour siblings'

Recommendation 17

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 stem cells. We recommend that the draft Bill be amended to substitute 'serious' for 'life-threatening'. (Paragraph 199)

41. The Government accepts the Committee's recommendation and will amend the Bill accordingly.

42. This recommendation is in line with the HFEA's current policy, which includes both serious and life-threatening conditions.[21] By accepting this recommendation, the Government believes it is in keeping with allowing the regulator greater flexibility, it would be left to the regulator to determine the meaning of 'serious' in exercising its discretion as to whether testing should be authorised in a particular case.

20 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, December 2006, Cm 6989, paragraph 2.16.

21 *Human Fertilisation and Embryology Authority Code of Practice*, 7th Edition, paragraph G.12.5.5.

43. The revised Bill, in line with the Committee's general call for greater flexibility, will replace reference to treatment by stem cells derived from umbilical cord blood only, with the possibility of treatment using other types of tissue and cells. In effect this would reflect in statute the HFEA's current guidance, which refers to the use of any histocompatible tissue.

Sex selection

Recommendation 18

Although we have heard some arguments in favour of sex selection for non-medical reasons and in some circumstances we recognise that it may not do harm, on balance we recommend that the draft Bill be amended in line with the HFEA's current policy. (Paragraph 205)

44. The Government notes the Committee's view that sex selection for non-medical reasons should not be permitted. The concerns raised by the HFEA reflect a minor drafting point that will be amended in the revised Bill in order to be in line with the HFEA's current policy.

45. The redrafted provision in the Bill will replace the reference to an abnormality affecting the X or Y chromosome with a reference to a link between gender and the serious medical condition of which there is a risk, rather than to a link between the chromosome and the genetic abnormality that may give rise to that condition.

Research licences

Recommendation 19

There is clearly some confusion surrounding the Government's decision to omit from the draft Bill the current provision which prohibits the genetic modification of embryos for research purposes. We make no determination on this point but we recommend that the Government clarifies its policy decision to allay the concerns which have been expressed. (Paragraph 212)

46. The 1990 Act currently prohibits altering the genetic structure of any cell while it forms part of an embryo,[22] but includes a regulation-making power to exempt certain circumstances from the restriction if necessary. The House of Commons Science and Technology Committee's 2005 review into the current legislation recommended that 'the absolute prohibition on genetic modification of the pre-14 day human embryo be removed for research purposes'.[23]

22 Schedule 2, paragraph 3(4).
23 *Human Reproductive Technologies and the Law*, House of Commons Science and Technology Committee, March 2005, HC 7-I, paragraph 82.

47. This was reflected in the 2006 White Paper, which states: 'The Government is not, however, convinced of the need to preclude research activities that would involve altering the genetic structure of the embryo, as part of legitimate research projects. This position is, in principle, already recognised in the legislation by the provision of a secondary legislative power. For research purposes only, the Government intends to remove the restriction on altering the genetic structure of a cell while it forms part of an embryo. Licensed research projects intending to undertake this activity would still be required to meet all the stringent controls applicable to embryo research projects including demonstrating that the use of embryos was necessary.'[24]

Consent to storage and use of gametes and embryos

Recommendation 20

We recommend that the Government should consider the concern raised by the HFEA in relation to donor gametes and the withdrawal of consent to the storage of an embryo. Subject to this, we support the provisions [on consent to storage and use of gametes and embryos] in Schedule 3 to the draft Bill. (Paragraph 215)

48. The intention of the provision in Schedule 3[25] of the draft Bill was to deal with situations where an embryo has been created using the gametes of two partners and not from any donor gametes. If an embryo was created using a woman's egg and donor sperm and the woman no longer wanted to consent to storage of that embryo it is not the intention that the clinic would have to notify the donor for consent to destroy the embryo, or to enter into any 'cooling-off' period. The Government hopes that this clarifies the point, and the provision in Schedule 3 will be redrafted to achieve this.

Recommendation 21

We agree with the Government that there should be some mechanism for allowing the storage of gametes in cases where an individual lacks the capacity to give consent, either through temporary mental incapacity or because of legal minority. We recommend that the Government consider more carefully the technical point raised by the Royal College of Pathologists; and consider making express provision for the circumstances in which it would be lawful to take gametes without explicit consent. This aside, however, we support the provisions on storage without consent. (Paragraph 218)

49. The intention of the relevant provision[26] is to allow for situations where the taking of gametes would be justified to protect the reproductive capacity of a temporarily incapacitated person, such as the sudden onset of serious illness or a major injury, where potentially life-saving treatment might impair the patient's future ability to have children which are genetically their own.

24 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)*, December 2006, Cm 6989, paragraph 2.52.
25 Schedule 3, paragraph 5, new subparagraph 4A to be inserted.
26 Schedule 3, paragraph 9.

50. A condition of storing gametes is that the person who provided them is expected to recover capacity.[27] There are no circumstances in which gametes stored under such conditions could be used for assisted conception treatment or embryo research without the written consent of the patient. For this reason, the scenario cited in the Royal College of Pathologists' written evidence could not occur in practice.

51. The Government believe it is vital that clinicians are able to exercise fully their professional judgement in determining, within the scope of the proposed legislation, when it would be in an incapacitated person's best interests to take gametes for storage. For that reason, we do not believe that a list of circumstances where gamete storage would be permitted would allow the flexibility needed to best serve patients in this situation.

The 'need for a father'

Recommendation 22

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 the requirement to consider the need of a child for a second parent should, as now, not be a barrier to treatment. (Paragraph 243)

52. The Government notes the Committee's balance of view in relation to section 13(5) of the 1990 Act and its recommendation for a free vote on this issue.

53. Section 13(5) imposes a mandatory condition on treatment licences, requiring 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.

54. The HFEA is required to provide guidance on this provision via its code of practice for licence-holders. In relation to the need for a father, the current guidance states:

Where the child will have no legal father the treatment centre is expected to 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.[28]

27 Schedule 3, paragraph 9, subparagraph 10(3)(c).
28 *Human Fertilisation and Embryology Authority Code of Practice*, 7th Edition, paragraph G.3.3.3.

55. 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.[29]

56. 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.[30]

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

58. 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.

Storage limits

Recommendation 23

We recommend that, in relation to gametes or embryos created or donated for research, the ten year limit should either be extended or removed. (Paragraph 249)

59. The Government remains convinced of the need for limits on the period of storage for gametes and embryos. In the draft Bill, the Government extended the statutory storage period for embryos from five to ten years to bring it into line with the storage period for gametes. There is a regulation-making power to extend these periods if necessary and the Government will keep this under review.

Recommendation 24

We also recommend that there should be a system of consent such that, at the commencement of fertility treatment, couples are asked for their consent that any gametes or embryos left unused for treatment at the expiry of the ten years become the property of the HFEA and may then be used for research purposes. At any point up to the 10 year limit, there should be the ability to withdraw consent so that gametes or embryos would be destroyed in accordance with patients' wishes. (Paragraph 250)

29 *Review of the Human Fertilisation and Embryology Act – A Public Consultation*, August 2005, paragraph 3.28.
30 *Human Reproductive Technologies and the Law*, House of Commons Science and Technology Committee, March 2005, HC 7-I, paragraph 101.

60. If donors die or cannot be traced, the issue of whether the right of use or disposal of remaining embryos should pass to the 'storage authority' is a matter that was considered and rejected early in the formation of the 1990 Act. The Government White Paper that followed the Warnock report set out the position that the 'storage authority' should not have the right of use or disposal unless specifically granted this by the donor.[31] The Government at the time concluded that the law should be based on the clear principle that the donor's wishes are paramount during the period in which embryos or gametes may be stored; and that after the expiry of this period, they may only be used by the licence-holder for other purposes if the donor's consent has been given. The Government continues to hold this position.

61. Introducing the Committee's recommendation would mean that before commencing treatment, a patient's consent would be required so that any embryos left over following treatment could be donated for research. Patients' views on this are liable to change during the course of treatment and, as such, the Government feels this is not something that can be agreed to beforehand. Currently, if embryos are no longer required for treatment, patients can choose at that stage to donate them to specific research projects. We believe that this strikes the right balance. In order to ensure fully informed consent, the patient is provided with details of the project so that they can decide whether they wish to donate.

Register of information

Recommendation 25

We recommend that the draft Bill be amended to extend to cohabiting couples and those planning intimate relationships the right of access to the register to find out whether they are related to the other person. We also recommend that the Government amends the draft Bill to require consent from the other person before access is provided. (Paragraph 256)

62. The 1990 Act allows for people intending to marry to contact the HFEA to enquire as to whether they may be related as a result of donor insemination. In the draft Bill, the Government widened this provision to extend to people intending to form civil partnerships. This provision is intended to prevent people from unknowingly entering into legally prohibited degrees of relationship.

63. The Government accepts the Committee's recommendation to extend this further to people planning intimate relationships and will amend the Bill accordingly. The Government also accepts the recommendation put forward by the Committee that consent from both parties should be required for this information to be provided.

Recommendation 26

We recommend that the draft Bill be amended to allow the HFEA to set up a voluntary contact register [for donor-conceived people]. (Paragraph 259)

31 *Human Fertilisation and Embryology: A Framework for Legislation*, November 1987, Cm 259, paragraph 51.

64. The HFEA currently holds a database ('the register') of all donor treatment carried out since the 1990 Act came into force on 1 August 1991.[32] The register holds information on patient treatment at fertility clinics, including where donor gametes or embryos are used. The aim of the register is to give donor-conceived people information about their genetic backgrounds and to help prevent biological relatives from inadvertently marrying or having children.

65. For donor treatment provided before the 1990 Act, the Government funds a voluntary contact register (UK DonorLink), which is currently run by After Adoption Yorkshire. The Government included a provision in the draft Bill to allow RATE to take up the running of this register. The revised Bill will include a provision to allow the HFEA to run the voluntary contact register, or to delegate the running of it.

Recommendation 27

We recommend that the age of access to the Register should be reduced to 16. (Paragraph 262)

66. The 1990 Act allows for donor-conceived people, on reaching the age of 18, to contact the HFEA to find out if they were donor-conceived and, if so, to be given certain details about the donor.[33] Donor anonymity was removed in 2005, so any donor-conceived person born as a result of treatment provided after that date can access identifying as well as non-identifying information (on reaching 18).

67. The Government intends to amend the Bill in order to reduce the age of access to the register for *non-identifying* information to age 16, but retain access to *identifying* information at age 18.

68. The Government believes that it would not be appropriate to reduce the age of access to *identifying* information for donor-conceived people whose donors have already donated identifiably. Those donors would have donated or re-registered on the basis that their identifying information would be given, if requested, to those aged 18 or above. We are also aware of concern that future donors may be deterred by the possibility of 16 rather than 18 year olds having access to identifying information.

32 Clause 31(1).
33 Clause 31(3).

Parenthood – birth certificates

Recommendation 28

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. We therefore recommend that, as a matter of urgency, the Government should give this matter further consideration. (Paragraph 276)

69. 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.'[34] 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.

Counselling/intermediary services

Recommendation 29

We recognise that, given the issues involved in the practical application of these provisions, counselling is important and we recommend that the Government should ensure that counselling services in these areas are available and have sufficient funding to provide services to all who require them. (Paragraph 278)

71. The Government agrees with the Committee that the availability of counselling is important.[35] We expect that the process by which the HFEA handles requests by donor-conceived people for information will be included in the discussions that the Government will have with the HFEA about its annual business plan and priorities.

34 *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, July 1984, Cm 9314, paragraph 4.25.
35 New clauses 31ZA and 31ZD.

Sperm-sorting kits

Recommendation 30

We recommend that clause 65 should be removed from the draft Bill. (Paragraph 284)

72. Clause 65 was a future-proofing measure, the intention of which was to ensure consistency with the general policy of not allowing sex selection for non-medical purposes, in the event that such kits were to become available in the future. However, the Government recognises the Committee's concerns about the practicalities of framing legislation now for potential developments in the future. The Government will remove this provision from the Bill and keep the matter under review.

Surrogacy arrangements

Recommendation 31

We recommend that the draft Bill be amended to bring the regulation of surrogacy within the remit of the HFEA. (Paragraph 289)

73. 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.

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