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

Session 2006–07

Human Tissue and Embryos (Draft) Bill

Volume I: Report

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

The Joint Committee was appointed to consider and report on the Human Tissue and Embryos (Draft) Bill published by the Department for Health on 17 May 2007 (Cm 7087). The Committee was appointed by the House of Commons on 2 May 2007 and the House of Lords on 8 May 2007.

Membership

The Members of the Committee were:

| | |
|----------------------------|---------------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Mackay of Clashfern | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Robert Key MP |
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| Lord Selsdon | Geraldine Smith MP |
| Lord Turnberg | Ms Dari Taylor MP |
| Lord Winston | Phil Willis MP (Chairman) |

Full lists of Members' interests are recorded in the Commons Register of Members' Interests <http://pubs1.tso.parliament.uk/pa/cm/cmregmem/041203/memi02.htm> and the Lords Register of Interests <http://pubs1.tso.parliament.uk/pa/ld/ldreg/reg01.htm>

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NOTE: References in the text of the report are as follows:

(Q) refers to a question in oral evidence

(Ev) refers to an evidence submission

The Report of the Joint Committee is published in Volume I, HC 630-I, HL Paper 169-I.

The Evidence of the Committee is published in Volume II, HC 630-II, HL Paper 169-II (published 8 August 2007).

ABSTRACT

The Human Tissue and Embryos (Draft) Bill, published on 17 May, sets out the Government's proposals to update the law on assisted human reproduction. A Joint Committee of both Houses of Parliament was set up on to undertake pre-legislative scrutiny on the draft Bill and ordered to report by 25 July.

Assisted reproductive technology, treatment and research have developed significantly since the Human Fertilisation and Embryology Act was passed in 1990. These developments have raised ethical, scientific, legal and social issues worthy of detailed consideration. We welcome the draft Bill and the opportunity to undertake pre-legislative scrutiny in this important area. However, there are a number of significant areas where we challenge the Government's approach.

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

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

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

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

Human Tissue and Embryos (Draft) Bill

CHAPTER 1: INTRODUCTION

The Joint Committee

1. The Joint Committee on the Human Tissue and Embryos (Draft) Bill was appointed by a motion of the House of Commons on 2 May 2007 and a motion of the House of Lords on 8 May 2007 with terms of reference “to consider and report on any draft Human Tissue and Embryos Bill presented to both Houses by a Minister of the Crown” and to “report on the draft Bill by 25th July 2007”.¹ The motions directed the Committee to meet for the first time on 15 May 2007. The Human Tissue and Embryos (Draft) Bill was duly presented to Parliament on 17 May 2007 sponsored by the Department of Health.²

Scope of our inquiry

2. In the time available for our inquiry we have necessarily had to prioritise some issues over others. We were advised by the Clerk of Public Bills in the House of Lords and the Clerk of Legislation in the House of Commons that, if a Bill in terms similar to the draft Bill were to be introduced, amendments relating to termination of pregnancy (abortion), the retention of tissue samples and presumed consent for organ donation would in principle be orderly. While we recognise that these are important issues, we took a decision at the start that abortion and presumed consent for organ donation would not form a specific part of our inquiry because they do not form part of the draft Bill. We do cover the retention of tissue samples in Chapter 5. We also acknowledge there are other important issues relevant to the debate, in particular recent developments in adult stem cell research, but again these have not formed part of our inquiry. We note that during our inquiry, the House of Commons Science and Technology Select Committee announced an inquiry into *Scientific Developments relating to the Abortion Act 1967*.

Timing

3. We welcome the decision to present this draft Bill for pre-legislative scrutiny although we note the limited time we were given to undertake our inquiry—just under 9 sitting weeks from the publication of the draft Bill (less than the recommended 12 sitting weeks).³ However, we have used the time available to undertake a thorough investigation of the draft Bill and make a number of recommendations in this report based on evidence we have received.

¹ Votes and Proceedings of the House of Commons Wednesday 2 May 2007, House of Lords Minutes of Proceedings of Tuesday 8 May 2007

² Cm 7087

³ Report of the Joint Committee on the Draft Charities Bill, September 2004, HL 167-I / HC 660-I. See also Report of the Joint Committee on the Draft Legal Services Bill, July 2006, HL 232-I / HC 1154-I, House of Commons Constitutional Affairs Committee Eighth Report of Session 2005–06, Reform of the coroners’ system and death certification, HC 902-I

Evidence and other views received

4. Despite the short timescale, we have sought a wide range of evidence to inform our Report and we would like to thank all those who gave us their views. We heard oral evidence from 46 witnesses comprising expert specialists, representatives of interested organisations and individuals. We held an evening discussion forum with 11 organisations representing particular moral and ethical perspectives and a report of this forum is published in Appendix 5. We had 115 submissions of written evidence. More than 100 other submissions were received. Some of these addressed abortion and other issues not under direct consideration by the Committee. Many more were inspired by a campaign by Christian Action Research and Education (CARE) and covered issues such as the need for a father provision (in relation to fertility treatment), the creation of inter-species embryos, human reproductive cloning and the regulation making powers of the Secretary of State.⁴ The Committee also conducted an online consultation on four questions via its website (a report of the online consultation is printed in Appendix 6). The House of Lords Delegated Powers and Regulatory Reform Committee assisted us by commenting on the delegated powers in the draft Bill (the Committee's advice is printed in Appendix 7). In producing our Report, we have sought to give due consideration to everything we have heard and read. A full list of witnesses is set out in Appendix 2 and a separate volume of evidence will be published to accompany this report.

Acknowledgements

5. We would like to record our thanks to our Specialist Advisers, Professor Martin Johnson, Professor of Reproductive Sciences, Department of Physiology, Development and Neuroscience at the University of Cambridge and Professor Sheila McLean, Professor of Law and Ethics in Medicine at the University of Glasgow, for their valuable input and assistance during the course of this inquiry.

⁴ Ev66, See also CARE special briefing: The draft Human Tissue and Embryos Bill, 25 May 2007, <http://www.care.org.uk/Publisher/article.aspx?id=79612> (correct as at time of publication)

CHAPTER 2: POLICY BACKGROUND

Policy history

6. It is nearly thirty years since the birth of the first child conceived using *in vitro* fertilisation (IVF). In light of scientific developments in the fertilisation and embryology field, a Committee of Inquiry was appointed in 1982, chaired by Baroness Warnock. The Committee's Report (the Warnock Report) published in 1984 concluded that there was an urgent need for a scheme of active monitoring and regulation in this area.⁵ Following a process of public consultation through Green and White Papers, Parliament passed the Human Fertilisation and Embryology Act 1990 (the 1990 Act) which implemented many of the recommendations of the Warnock Report and in particular provided a legislative framework for:
 - The creation of human embryos outside the body and their use in treatment
 - Use of human embryos in research
 - Use of donated gametes and embryos
 - The establishment of the Human Fertilisation and Embryology Authority (HFEA) with responsibility for licensing, monitoring, information and advice on human embryo research and assisted reproduction treatment.
7. The 1990 Act has since undergone a series of modifications. In 1992, some of the information disclosure restrictions in the original Act were revised after they were found to be overly restrictive.⁶ In 2001, the purposes for which embryo research could be licensed were extended to include "increasing knowledge about the development of embryos", "increasing knowledge about serious disease", and "enabling any such knowledge to be applied in developing treatments for serious disease", thus paving the way for embryonic stem cell research.⁷ Meanwhile, in 2001 the Human Reproductive Cloning Act was passed outlawing any attempt to create a child through a process other than fertilisation using sperm and egg. In 2004, Parliament agreed that donor-conceived children would be able to access the identity of their sperm, egg or embryo donor on reaching the age of 18.⁸
8. There have also been developments in the law on human tissue. Following a 2002 Department of Health review of the law on human organs and tissues, the Human Tissue Act 2004 established the Human Tissue Authority (HTA). Also in 2004, the European Union Tissue Directive set EU-wide standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue

⁵ Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, Cm 9314

⁶ Human Fertilisation and Embryology (Disclosure of Information) Act 1992

⁷ The Human Fertilisation and Embryology (Research Purposes) Regulations 2001

⁸ Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004

and cells.⁹ The Scottish Parliament passed the Human Tissue (Scotland) Act in 2006.

9. Separate from this legislative process, the Department of Health undertook a review of its ‘arm’s length bodies’ in an effort to improve efficiency and cut bureaucracy.¹⁰ One of the conclusions of this review was a proposal to replace, by April 2008, the HFEA and the HTA with a single body with responsibilities across the range of human tissue and cells, to be known as the Regulatory Authority for Tissue and Embryos (RATE). Proposals for RATE form Part 1 of the draft Bill.
10. In 2005 the House of Commons Science and Technology Select Committee published a report on *Human Reproductive Technologies and the Law*.¹¹ The preceding inquiry investigated the legislative framework provided by the 1990 Act and challenges presented by technological advance and “recent changes in ethical and societal attitudes.” In light of the Committee’s Report, and legislative changes that had already been made, the Department of Health undertook a review of the 1990 Act.
11. The Government’s rationale for this review was that:

“The [1990] Act has stood the test of time well, and is a tribute to the foresight of its creators ... The Act and the regulatory system it established have instilled public confidence in the safe and ethical use of assisted reproduction technology subject to appropriate safeguards. However, it was never expected that the Act would remain forever unchanged in this area of fast-moving science.”¹²
12. The Government conducted a public consultation exercise in 2005 and received 535 formal responses from around 100 stakeholder groups and organisations and a wide range of individual professionals, patients and members of the public. An independently commissioned summary of responses was published in March 2006.¹³ In December 2006, the Department of Health responded with its proposals for revised legislation in a White Paper.¹⁴ In 2006, the House of Commons Science and Technology Select Committee began an inquiry into the proposals in the White Paper for the regulation of hybrid and chimera embryos reporting in March 2007. Table 1 provides a chronology of relevant legislation, reviews, reports and events.

⁹ Directive 2004/23/EC of the European Parliament and the Council of the European Union. Secondary legislation implementing the Directive was passed in April 2007.

¹⁰ Report on Reconfiguring the Department of Health’s Arm’s Length Bodies, Department of Health, July 2004

¹¹ House of Commons Science and Technology Committee, Fifth report of Session 2004–05, *Human Reproductive Technologies and the Law*, HC 7–1

¹² Review of the Human Fertilisation and Embryology Act: A Public Consultation, Department of Health, 2005

¹³ Report on the Consultation on the Review of the Human Fertilisation and Embryology Act 1990, prepared for Department of Health. People Science and Policy Ltd, March 2006

¹⁴ Review of the Human Fertilisation and Embryology Act, Department of Health, December 2006

TABLE 1
Chronology of relevant legislation, review and reports

| | |
|----------------|--|
| July 1978 | Birth of the first child conceived using IVF |
| July 1984 | Report of the Committee of Inquiry into Human Fertilisation and Embryology (the Warnock Report) ¹⁵ |
| July 1985 | Surrogacy Arrangements Act (c. 49) |
| November 1990 | Human Fertilisation and Embryology Act (c. 37) |
| August 1991 | Human Fertilisation and Embryology Authority (HFEA) established. |
| July 1992 | Human Fertilisation and Embryology (Disclosure of Information) Act (c. 54) |
| January 2001 | The Human Fertilisation and Embryology (Research Purposes) Regulations ¹⁶ |
| December 2001 | Human Reproductive Cloning Act (c. 23) |
| February 2002 | Report of the House of Lords Select Committee on Stem Cell Research ¹⁷ |
| September 2003 | Human Fertilisation and Embryology (Deceased Fathers) Act (c. 24) |
| March 2004 | EU Tissue Directive (EU 2004/23/EC) |
| July 2004 | Department of Health Report on Reconfiguring the Department of Health's Arm's Length Bodies |
| November 2004 | Human Tissue Act (c. 30) |
| March 2005 | House of Commons Science and Technology Committee Report on <i>Human Reproductive Technologies and the Law</i> ¹⁸ |
| August 2005 | Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law ¹⁹ |
| August 2005 | Publication of the Government's <i>Review of the Human Fertilisation and Embryology Act: a public consultation</i> |
| March 2006 | Publication of an independent summary of responses to the Review of the Human Fertilisation and Embryology Act: a public consultation ²⁰ |
| March 2006 | Human Tissue (Scotland) Act 2006 |
| December 2006 | Publication of the Government's White Paper: <i>Review of the Human Fertilisation and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)</i> ²¹ |
| March 2007 | House of Commons Science and Technology Committee Report: <i>Government proposals for the regulation of hybrid and chimera embryos</i> ²² |
| July 2007 | Human Fertilisation and Embryology (Quality and Safety) Regulations ²³ |

¹⁵ Cm 9314

¹⁶ S.I. 2001 No. 188.

¹⁷ Report of the House of Lords Select Committee on Stem Cell Research, Session 2001-02, HL 83(i)

¹⁸ Fifth report of Session 2004-05, HC 7-I

¹⁹ Cm 6641

²⁰ People Science and Policy, http://www.peoplescienceandpolicy.com/downloads/FINAL_HFEA_reportDH.pdf (correct at time of publication)

²¹ Cm 6989

²² Fifth report of Session 2006-07, HC 272-I

Parliamentary involvement

13. As the Minister of State for Public Health, Caroline Flint MP, suggested in oral evidence, parliamentary involvement has been key to the process of developing and revising legislation in this area. (Q 483) We have already noted the two recent House of Commons Science and Technology Committee reports. We also acknowledge other significant contributions to the debate on aspects of this subject, in particular the House of Lords Committee on Stem Cell Research, appointed in March 2001 “to consider and report on the issues connected with human cloning and stem cell research arising from the Human Fertilisation and Embryology (Research Purposes) Regulations”.²⁴ We note the importance of parliamentary involvement in policy development to date, and welcome the Minister’s promise that the Government “will carry on listening up until the point at which the Bill comes back and beyond.” (Q 484)

²³ Draft Statutory Instrument 2007

²⁴ Report of the House of Lords Select Committee on Stem Cell Research, Session 2001-02, HL 83(i)

CHAPTER 3: PUBLIC OPINION AND PUBLIC UNDERSTANDING

Public Opinion

14. During the course of our inquiry, many claims have been made about public opinion supporting one approach or another. We offer the following examples. Sir Liam Donaldson, Chief Medical Officer, in explaining the justification for the policy on inter-species embryos, noted “a feeling that this would be a step too far as far as the public are concerned”. (Q 244) The Lawyers’ Christian Fellowship told us that their concerns were “shared by our members ... and the public at large” and that they “believe that a fully informed public would agree that this sort of research [into inter-species embryos] should be banned”. (Ev52) Professor David Albert Jones, Professor of Bioethics at St Mary’s University College, referred to “the public resistance to making human non-human hybrids”. (Ev42)
15. Few of these witnesses offered serious evidence for their claims. Mark Henderson, Science Editor of The Times said “I think you are absolutely right that there is no evidence for what the public thinks of this at all beyond the absence of a massive response and a massive postbag ... which to me rather indicates indifference and perhaps a lack of really strongly held views. I accept that there are plenty of people who do have strongly held views but I do not think there is evidence either way.” (Q 286)
16. Sense About Science highlighted that the Government had justified its policy position on the basis of “public unease” or “disquiet” but argued that the Department of Health’s consultation was not sufficient evidence to support such statements:

“In fact, the response to the Department of Health’s consultation in 2005 does not support the distinction that the proposed legislation makes on human-animal chimera or hybrid embryos. As the Commons Science and Technology Committee commented in their recent Fifth Report, out of the 277 objections raised in that consultation, 227 were against human embryo research in general.” (Ev71)²⁵
17. Some attempts, however, have been made to measure public opinion. The HFEA undertook a public consultation exercise in 2002 on whether sex selection of embryos for non-medical reasons should be permitted. This involved both qualitative research (conducted through discussion groups) and quantitative research (which focussed on issues arising from the qualitative research). This qualitative research surveyed a representative sample of the UK population (2,615 adults). By contrast, the public consultation that was also carried out drew 600 responses. (Ev12(a), Appendix B) Angela McNab, Chief Executive of the HFEA, told us it had “found that largely, very overwhelmingly, the public in this country were opposed to sex selection for non-medical reasons” and claimed that its policy on sex selection has public support on the basis of this public consultation. (Q 222 and Ev12, para 19)
18. In 2002 the Medical Research Council commissioned a consultation on public attitudes to stem cell research, involving 12 focus groups run in eight

²⁵ House of Commons Science and Technology Committee, Fifth Report of Session 2006–07, HC 272-I

English towns.²⁶ In July 2004 the Human Genetics Commission launched a public consultation paper *Choosing the Future: genetics and reproductive decision-making* and received 196 written responses.²⁷ Other studies include: a MORI poll conducted in 2005 on who should be involved in decisions about the embryo; a 2005 *You Gov/Daily Telegraph* Survey on Abortion, Euthanasia and Cloning; and the HFEA Report on Public Attitudes to Fertility Treatment, Embryo Research and the Regulation of this Work—Preliminary Findings from the UK 2005, based on the results of the 2005 MORI poll²⁸.

19. Some witnesses did refer to this polling and consultation as an evidence base.²⁹ For example, Professor Colin Blakemore, Chief Executive Officer of the Medical Research Council (MRC), relied on 2003 MORI poll to “draw attention to the fact that from the latest opinion poll 70 per cent of the public are fully supportive of the use of human embryos; there has not been an outcry in the press—and this is perfect fodder for sensational coverage in the press and it has not happened very much.” (Q 39)
20. The Royal Society noted in evidence that “Parliament and the regulatory bodies will need to consider the balance between representative public engagement, and engagement with stakeholder and interest groups”. It continued:

“The techniques used [for public engagement] must be methodologically rigorous, based on principles of effective public engagement, and any support material must be scientifically sound. Meeting these conditions will require a corresponding level of funding and allocation of time. Centrally commissioned and organised public engagement is advantageous, particularly where it is linked to a particular issue where policy is being developed. However, providing that it meets the conditions outlined above, engagement activities undertaken independently in other sectors (e.g. learned societies, civil society and academia) may also be taken into account.” (Ev 59)³⁰
21. Whether or not these are adequate mechanisms for measuring public opinion is open to debate. Polling questions on complicated scientific issues can be over-simplified, particularly if they require a ‘yes-no’, or ‘multiple choice’ answer. The House of Lords Select Committee on the Assisted Dying for the Terminally Ill Bill considered this problem and noted that Parliament must “assess to what extent opinion research based on answers to questions placed with little surrounding context represents a sound basis for changing the law.”³¹ Responses to public consultations often come from those with strong views which may not be representative of those held by the general public. Those who reply to public consultations are by their nature self-selecting. Even if a majority view can be identified, we note the words of HLA Hart that “It seems fatally easy to believe that democratic principles entail

²⁶ http://www.peoplescienceandpolicy.com/projects/national_stemcell.php

²⁷ http://www.peoplescienceandpolicy.com/projects/genetics_reproductive.php

²⁸ Q296, Ev71, para 3.2, http://www.yougov.com/archives/pdf/TEL050101042_1.pdf (Correct at time of publication), http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-D99BE804/hfea/2005-01-07_FINAL_European_Consortium_EACC_public_attitudes_to.pdf (Correct at time of publication)

²⁹ Ev09. See also Ev71, para 3.2

³⁰ See also Q282

³¹ Report of the Select Committee on the Assisted Dying for the Terminally Ill Bill, April 2005, HL 86-1

acceptance of what may be termed moral populism: the view that the majority have a moral right to dictate how all should live”.³²

22. We have heard some strongly held views during the course of our inquiry and recognise and respect that everyone is entitled to their opinion. However, we are concerned by the unsubstantiated claims made about public opinion and public support and by the lack of evidence provided. Where organisations claim to speak on behalf of the public, they should have a proper research basis to do so that is capable of scrutiny. The Government should take steps to increase its involvement with both qualitative and quantitative social science research to provide an underpinning to our understanding of public opinion in this field.
23. Legislation in an area such as this needs a sufficient level of support from the public and this requires a corresponding understanding of public attitudes. **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.**

Public education and public understanding

24. Key to public opinion is public education and public understanding. In order to explore some of the issues around public education and public understanding, we heard evidence from a panel of journalists. Tom Feilden, Science and Environment Correspondent for the BBC Radio 4 Today Programme, told us that “talking to people, going out and interviewing people ... is how you would get a feel for public acceptance of a particular idea or a particular avenue of research”. (Q 283) In relation to public response to media coverage he said:
- “the sort of response you get directly in terms of emails or letters ... tend to be from the two extremes and that is possibly because it is a self-selecting process—you only get people who are particularly outraged or who are particularly happy who feel the need to respond ... What the wider public are thinking is harder to get at.” (Q 282)
25. Fergus Walsh, the BBC Medical Correspondent told us of the challenges of public education: “We have to take very complex issues and explain it to a lay audience ... if it is over complex then the audience will switch off—in my case literally—and you have to make that reporting engaging without being superficial”. (Q 284) Additionally, Mark Henderson told us that “Our main job is to report the science and historically ... stories like this always got subsumed by the ethical debate” but that “there has been much more maturity about that recently”. (Q 292)
26. We were impressed with some of their evidence and recognise the valuable role journalists play in promoting public understanding of the key issues in science, but it is not their duty to do so. We believe, however, that it is the duty of scientists, the academic community, the regulatory bodies and ultimately the Government. We note the House of Commons Science and Technology Committee Report on *Scientific Advice, Risk and Evidence Based*

³² H L A Hart, *Law, Liberty and Morality*, Oxford, Oxford University Press, 1963, page 79

Policy Making which made detailed recommendations in this area.³³ **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.**

Parliament's role

27. Parliament's role in a representative democracy is to make a collective judgement about what the legislation should say, even though it may not have a clear understanding of public views. We hope in this Chapter to have highlighted the difficulties of effectively gauging public opinion and the need for a balanced approach to what information we do have on public opinion. Although we acknowledge that public opinion or, more accurately, perceptions of public opinion underpin many of the arguments in this field, our task is to produce a Report based on the evidence we have received.

³³ House of Commons Science and Technology Committee, Seventh Report of Session 2005–06, *Scientific Advice, Risk and Evidence Based Policy Making*, HC 90I

CHAPTER 4: LEGISLATIVE AND ETHICAL FRAMEWORK

The ethical framework

Warnock and the 1990 framework

28. The Warnock Report set out a number of principles that provided an ethical framework for the debate leading to the Human Fertilisation and Embryology Act 1990 (the 1990 Act). Those principles included: according a special status to the embryo; permitting human embryo research only under licence from a regulator; and placing a 14-day limit on that research. We heard differing views on the extent to which the Warnock Report still provides an appropriate ethical underpinning for legislation on human fertilisation and embryology. The Chief Medical Officer, Sir Liam Donaldson, told us that one of the “trump cards” was “a very good system of regulation in place, set out initially by a very wise bird, Mary Warnock, who I think looked at the whole thing very, very carefully”. (Q 230) However, he also told us that “We have had, generally, in this country a deficit in medical ethics, both in the input to some of our decisions over the years and, also, in medical ethicists” (Q 228).
29. Professor Colin Blakemore, Chief Executive Officer of the Medical Research Council, argued that the “guiding view, the permissive legislation, plus clear prohibition of certain steps beyond which research should not proceed, is a very useful one” (Q 3). Hugh Whittall, Director, Nuffield Council on Bioethics, thought that the Warnock framework was “still an appropriate model”. (Q 5)³⁴
30. Other witnesses, however, argued that things had moved on since 1990 and that the ethical framework had been challenged by scientific advances. Mark Henderson, Science Editor of *The Times* told us that while the flexibility of the 1990 Act was “a big bonus” what had changed since 1990 was “that science—science as a whole and medical science in particular—has become much more of an issue for people” and has “moved on in ways that could never have been predicted at the time”. (Q 275) Professor Alison Murdoch, Professor of Reproductive Medicine at Newcastle Fertility Centre, thought that the 1990 Act “was appropriate for its time but as science and society have developed, fundamental flaws have become apparent and need to be addressed.” (Ev17) Roger Brownsword, Professor of Law at King’s College London, argued that there were two areas in which there was a need to re-think the Warnock approach: whether in 2007 it remained appropriate to have reproductive treatment, non-reproductive treatment and research under the same legislation and the same regulator; and whether the essentially utilitarian approach remained appropriate with the political culture more committed to a human rights agenda. (Q 2)
31. We also heard differing views about the Warnock approach to the special status of the embryo. While some continued to support Warnock’s gradualist approach to the developing moral status of the embryo, others favoured an absolutist position, such that an embryo at any stage of development should be viewed as a human and afforded respect and protection.³⁵

³⁴ See also Q 61, Q 62

³⁵ See Evening Forum Report, Appendix 5, Scottish Council on Human Bioethics, Ev25, Joint Ethico-Medical Guild of Catholic Doctors and the Catholic Union of Great Britain, Ev45, para 7, Catholic Parliamentary Office, Ev72, para 1

The ethical framework in the draft Bill

32. Most witnesses who commented on the ethical framework in the draft Bill did so in negative terms. Professor Raanan Gillon, Emeritus Professor of Medical Ethics at Imperial College London, told us that the draft Bill provided a very legalistic framework and he “[did] not think there is a strong ethical framework within the [draft] Bill and I think that is a pity”. (Q 806) Professor John Haldane, Professor of Philosophy and Director of the Centre for Ethics, Philosophy and Public Affairs at the University of St Andrews, similarly did not consider the draft Bill had a strong ethical underpinning and said “people are trying, as best they can, to fabricate legislation ... but not within the framework of a systematic understanding of what the basic ethical principles and values might be”. (Q 807) According to Professor Søren Holm, Professorial Fellow in Bioethics at Cardiff Law School, and Professor of Medical Ethics at the University of Oslo, although there was in a sense an ethical framework implied by the moral status of the embryo, the draft Bill “does not have a framework for how you should think about the ethical issues that are going to arise in the future”. (Q 808)
33. Several witnesses argued that the provisions of the draft Bill devalued the central principle of Warnock—the special status of the embryo. Professor Margaret Brazier, from the Centre for Social Ethics and Policy in the University of Manchester School of Law, argued that much of the draft Bill rejected the principle of respect for embryos embodied in the 1990 Act. (Ev109) Paul Tully, General Secretary of the Society of the Protection of Unborn Children (SPUC) and Dr Donald Bruce, Director of the Church of Scotland Science, Religion and Technology Project, argued that there was a sense in which the special status of the embryo was under threat. (Evening Forum Report, Appendix 5) Professor Holm argued that “since 1990 the concept of ‘respect for the embryo’ had been diluted, with actual practice moving further and further away from what is acceptable to those who are ‘conservative’ on these issues”. (Ev111)

A statement of principles?

34. Several witnesses supported the inclusion of an explicit statement of ethical principles in the draft Bill.³⁶ Professor Gillon told us he was committed to a simple ethical framework with four principles: “beneficence, non-maleficence, respect for autonomy and justice ... that plus the question of their scope of application plus the crucial question of what you do when they conflict gives you a reasonable outline of the scope of ethics”. (QQ 806, 841, 848) He also suggested looking to the UNESCO universal declaration on bioethics and human rights, although he noted that this framework excluded “one crucial issue, and that is the moral status of the embryo”. (Q 806) The Scottish Council on Human Bioethics additionally pointed to the Council of Europe’s Convention on Human Rights and Biomedicine³⁷, adding that they thought it should be signed and ratified by the UK. (Ev25) We note that there are a number of reasons why the United Kingdom Government has not ratified the Convention, including that the Convention includes a ban on creating embryos for research purposes, contrary to the 1990 Act.

³⁶ See for example Ev29, para 3.1, Ev37, para 3.1

³⁷ Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4.IV.1997

How ethical decisions are currently made

35. Shirley Harrison, Chair of the HFEA and the HTA, told us that both organisations “obviously deal with major ethical issues all the time and the HFEA has an Ethics and Law Group which is advisory to it and that looks at any specific ethical issues”. In the HTA ethical issues were “a strand within all of the licensing codes”. (Q 168) The HFEA also has a “horizon scanning panel ... which meets two or three times a year and looks at potential future issues that might be coming up in science.” (Q 182) To gain a wider ethical input, the HFEA often supplements its Ethics and Law Group with additional expertise. Angela McNab, Chief Executive of the HFEA, told us that the HFEA Ethics Committee often “draw[s] in through co-opting a range of wider experience than we would be able to draw just from Authority members ... What it does is it gives us a deeper or richer texture to the discussions and debates that take place in the Ethics Committee ... I think the model we have works very well”. (Q 169)
36. We received some criticism, particularly from faith-based organisations, about the HFEA’s current approach to ethics in decision making. A particular criticism was of the breadth of ethical representation within the HFEA. For example, the Rt Revd Dr Lee Rayfield, Bishop of Swindon, and representative of the Church of England Mission and Public Affairs Council, noted that those who took an absolutist view of the rights of embryos were currently excluded from ethical decision-making in this area. (Evening Forum Report, Appendix 5) Professor Holm argued there was “no voice in the regulator for those who find the developments most contentious and not much engagement with those groups on the part of the HFEA”. (Ev111) Others, for example the Evangelical Alliance argued that ethics had been substantially marginalised. (Ev81) Professor Sir Ian Kennedy, Emeritus Professor of Health Law, Ethics and Policy, School of Public Policy, University College London, and Chairman of the Healthcare Commission, said he had concerns about the HFEA’s dual role in inspection and “thinking about really deep issues of bioethics”. (Q 744)

Ethics within the regulatory framework

37. We heard a range of suggestions of how to build ethics effectively into the structure of the new regulator, RATE. Several witnesses proposed that RATE should establish a separate ethics committee or similar. The Rt Revd Dr Lee Rayfield, Bishop of Swindon, noted that new research processes had caused difficult circumstances for the ethical advisors within the existing regulator and would not like to see RATE suffer the same problems. (Evening Forum Report, Appendix 5) The British Association for Tissue Banking thought that “significant attention [should be] paid to whether ethics should be dealt with by a single specialist panel reporting to the authority”. (Ev10, para 12) The UK National Stem Cell Network said that the ethical framework “must be engineered by RATE, which should use its powers to set up appropriate sub-committees comprised of expert individuals who are not necessarily part of the Authority’s existing infrastructure”. (Ev41, para 3) The HFEA proposed an ethics subcommittee on the same lines as the HFEA’s current Ethics and Law Committee. (Ev12(a), para 9)
38. Gareth Jones, Director of Scientific Development at the Department of Health, told us that it would be the RATE board “who would look at that advice and take decisions, partly from a wider perspective in terms of social

and legalistic perspectives”. (Q 498) The Minister noted that one of the difficulties in defining the membership of such a board was “which lay people should be on that board. We have some opinion in this country, and some very strong views in relation to the use of embryos both for IVF and research purposes ... of course we have to look at these issues. It is a mixture of science and ethics in these areas and part of getting the ethics right is taking public opinion with you in terms of support for the science”. (Q 503) We did not find this convincing.

39. Others favoured an ethics committee more detached from the regulator. The Church of England Mission and Public Affairs Council favoured “an Ethics Committee, working closely with but not controlled by the HFEA/RATE, on which a broad range of views were represented” and said the constitution of this committee “should include representatives of those who cannot serve on HFEA/RATE because of their clear opposition to embryo research. We feel that such viewpoints should not be marginalised or ignored”. (Ev68, para 3)
40. This desire for a wider breadth of representation, in response to criticism of the current system was echoed by others. Professor Gillon thought that if the Government went ahead with RATE, “it ought to have people with some ethics expertise, probably three of them at least from different perspectives”. (Q 827 and 829) However, the HTA thought that “RATE should decide the appropriate mechanism for taking advice on the diverse and complex ethical issues which it will undoubtedly need to consider”. (Ev11, para 16)

Ethics outside the regulatory framework

41. We also heard a range of views suggesting that ethical input should come from outside the regulator, in particular on whether a National Bioethics Commission (or Committee) should be established. Lord Brennan strongly supported a National Bioethics Council created on a statutory basis, with a diverse membership, supported by public money and separate from government and agencies. (Ev73) Several organisations also supported a national ethics committee, either to meet a gap in the draft Bill, or to overcome the inherent conflict of a regulator funded through licence fees also being required to ensure a broad range of ethical perspectives.³⁸ Professor Gillon told us “I think [a National Bioethics Committee] is a good idea myself but there are plenty of arguments against it” and noted that the Nuffield Council on Bioethics acted as a *de facto* National Bioethics Committee. (Q 805) The Medical Ethics Alliance thought it would have been helpful if a specific committee had been set up to consider ethical matters either before or in parallel with this consultation (Ev13)
42. Several witnesses noted opposition from the Department of Health to a National Bioethics Committee. Professor Haldane argued that the case for a National Bioethics Committee with a remit much larger than embryology questions “is really pretty much overwhelming and has been for quite some while ... the only significant opposition is from the Department of Health” (Q 807). Professor Sir Ian Kennedy said that “It is no secret that I proposed a National Bioethics Commission ... over 25 years ago. I have never changed my mind on that although I know that equally there are members of the Department of Health who have not changed their minds either”. (Q 763)

³⁸ Ev86, Dr Daniel Boucher (Evening Forum Report, Appendix 5), Ev15, Ev23, section A, Ev52, para 3

43. The Minister told us “I do not think we have changed our mind on that” and “the reason we have not changed our mind is because we feel still that things like the Human Genetics Commission, other advisory groups, the HFEA, all in their own way provide a great deal of advice and questions that we have to deal with, as well as the various parliamentary committees that meet, including the [Commons] Science and Technology Committee and others, to inform debate”. (Q 481) Ted Webb, Director of Scientific Development and Bioethics at the Department of Health, added “I am not aware of an international bioethics commission that works in any better way”. (Q 486)

Conclusions

44. We are concerned that the draft Bill lacks the explicit underpinning ethical framework which in 1990 was provided by the Warnock Report. Whilst we accept that the Warnock Report still provides a partial ethical framework, we agree with those who argue that scientific developments have made ethical decisions more difficult. Public consultation on individual issues is not a substitute. As a result, the draft Bill gives the impression of tinkering with existing legislative provisions rather than going back to first principles and seeking to take an overall view of where to go in the next 15 years or so. We cite as examples, the Government’s shifting approach to the regulation of inter-species embryos and the mixed messages from its approach to parenthood and the welfare of the child (see chapters 6 and 7).
45. Sir Liam Donaldson told us that asking ethicists to join a co-opted discussion [at the HFEA] “would not mean that they were unlikely to express an opinion, or feel compromised ... I think they would see it as a national duty to the population to get their advice right”. (Q 229) While we do not disagree, we are not persuaded that such ad hoc arrangements provide the necessary ongoing representation of diverse views and we are persuaded of the need to include a wide range of ethical views in this discussion.
46. We have given much consideration to how to address these concerns. In doing so, we have been mindful of the fact that the regulator is first and foremost a statutory body with responsibility to administer the law and to report to Parliament. However, it also has a secondary function to promote debate and education on matters pertinent to its remit and to advise the Secretary of State, and through him Parliament, on matters including ethical issues that may arise and that may influence future legislation. The primary ethical framework within which the regulator operates must, however, be set by Parliament.
47. We recognise that certain ethical views we have heard are incompatible with the ethical framework underpinning both the 1990 Act and the draft Bill and we recognise that those with such public views cannot administer the law to which they may be fundamentally opposed in principle. We would, however, seek to ensure that those holding these views continue to be engaged in discussion about future legal provisions, including this draft Bill and in the wider debate about bioethics, including in the work of the joint committee on bioethics recommended in paragraph 48.
48. We are unable to support proposals for a national bioethics committee. **Ultimately it must be for Parliament to set the ethical framework, taking the widest range of advice. We consider that an ethical input should be found from within Parliament and we recommend that Parliament should establish a joint bioethics committee of both**

Houses to provide ethical input to legislation raising significant issues in bioethics, such as the current draft Bill.

The regulatory architecture: getting the balance right

49. As well as requiring an appropriate ethical framework, the draft Bill should set an appropriate, consistent and workable regulatory architecture which achieves the right balance of responsibilities between Parliament, the regulator, clinicians and individuals. The Minister told us she was also seeking that balance. (Q 519) This means finding the right balance between flexibility and legal certainty. Hugh Whittall said that it was “for Parliament to decide what the starting point is where the line is drawn between the detail in statute and the flexibility at the outer end”. (Q 17)³⁹
50. Much of the debate in evidence centred on the degree of flexibility required. Some witnesses considered that the provisions in the draft Bill were overly prescriptive or prohibitive and favoured a more flexible approach. Hugh Whittall told us, in the context of whether Parliament should legislate for future developments, that “Parliament should [set] the scope of the regulatory framework and [set] down the general principles and standards by which the regulatory authority should work”. (Ev05(b)) The Royal College of Pathologists were concerned about what they saw as “a strategy of legislating negatively” which “gives the impression that practitioners in this field are not to be trusted and that professional guidance is inadequate”. (Ev06(2), para 2)
51. Most witnesses supporting greater flexibility did so in the hope of future-proofing the legislation. Dr Mark Hamilton, Chair of the British Fertility Society, told us that “the critical thing for those developing the legislation is it has to retain flexibility for what is unknown for the future in terms of developments and also unknown in terms of public and societal attitudes”. (Q 409) Fergus Walsh, Medical Correspondent for the BBC, told us of concerns expressed by many scientists that “if Parliament tries to second guess things now and specifically outlaws things now then they will be caught out five years down the line and really it should be left to whatever body regulates this area to have the power to issue licences”. (Q 302) Professor Colin Blakemore expressed concern that a draft Bill that is “fundamentally prohibitionist and then allows certain things under licence will not be capable of responding flexibly to developments in science”. (Q 15) Professor Brownsword supported “the way that the draft Bill has tried to build in some more flexibility through the regulation making powers that would anticipate changes that might come downstream”. (Q 16)
52. Others supporting the principle of flexibility did so in order to allow more freedom of action for regulators or clinicians. Professor Neva Haites, Chair of the HFEA Scientific and Clinical Advances Group and Professor in Medical Genetics, University of Aberdeen, told us that Parliament should provide “a broad, strong framework in which the regulator can then regulate.” (Q 622) David Gollancz, a donor-conceived person, felt that the draft Bill “confers too little flexibility on the regulators themselves to respond to technological changes”. (Ev44) The British Fertility Society suggested that revised legislation “must allow for sufficient flexibility to permit clinicians

³⁹ See also Ev26, para 6, Ev06, Ev09

and researchers to operate within a supportive regulated framework which does not inhibit innovation”. (Ev23, section A)

53. Others, however, argued that the draft Bill was too flexible. The most serious concern for Comment on Reproductive Ethics (CORE) was the “very deliberate flexibility and permissiveness” built into the provisions allowing the Secretary of State to make regulations. (Ev79, para 1.5) Dr Donald Bruce of the Church of Scotland thought that the question of whether Parliament or the regulator should decide a particular issue depended on the nature of the issue and its gravity. (Evening Forum Report, Appendix 5). The Scottish Council on Human Bioethics felt that “legal provisions should state only what is specifically acceptable, thereby prohibiting all other procedures”. (Ev25, para 2)
54. Many who supported this approach advocated a greater degree of parliamentary control. Andrea Minichiello-Williams, Public Policy Director of the Lawyers’ Christian Fellowship, thought that Parliament, not the regulator, should have the final say on the regulation of any new, scientific developments. (Evening Forum Report, Appendix 5) The Free Church of Scotland said that “Parliament should retain as much control as possible”. (Ev24, para 2) The Scottish Council on Human Bioethics said that legislation should “provide Parliament with greater powers to debate and amend the law” (Ev25, para 2).⁴⁰
55. We recognise that there is a balance to be struck between legal certainty and flexibility. In the draft Bill, the Government has favoured legal certainty. In doing so it has, in our view, been over-prescriptive in many areas in an attempt to provide for every eventuality. We favour a more flexible approach within clearly defined parameters. Legislation of this sort is difficult to future-proof. In taking this permissive view, we recognise that this approach will be open to broader interpretation and, perhaps, more frequent challenges in the courts.
56. **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 a 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 judge applications for research grants and we recommend that 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.**

⁴⁰ See also Ev27, Ev55, para 2, Ev74, para 5 and Ev76

CHAPTER 5: PART 1 OF THE DRAFT BILL—THE REGULATORY AUTHORITY FOR TISSUE AND EMBRYOS

Introduction

57. The merger of the Human Fertilisation and Embryology Authority (HFEA), the Human Tissue Authority (HTA) and some functions of the Medicines and Healthcare Products Regulatory Agency (MHRA) to form the Regulatory Authority for Tissue and Embryos (RATE) was first proposed by the Department of Health's review of arm's length bodies in 2004. The provisions covering RATE are set out in Part 1 of, and Schedule 1 to, the draft Bill, and include: the designation of RATE as the competent authority for the implementation of the EU Tissue Directive⁴¹; the appointment of the Chair of RATE (by the Secretary of State) and a board, of which at least half of the members must be lay members; and the appointment of at least three Expert Advisory Panels (EAPs) to advise RATE (on reproductive medicine and embryo research; anatomy and pathology; and blood and transplantation).
58. On 1 January 2007, Shirley Harrison was appointed Joint Chair of the HFEA and the HTA to “oversee the work of both Authorities until—pending legislation—the new Regulatory Authority for Tissue and Embryos (RATE) is established.”⁴² Shirley Harrison had been a member of the HTA since 2005, and its interim Chair since 2006 and, as she told the Committee, the merger had been in mind since the HTA's inception in 2005. (Q 155) In evidence to the committee, the HFEA and the HTA both argued that it was their responsibility “to plan on the basis that RATE is likely to go ahead” and that they were already working together to streamline regulation in this area. (Ev11(a) and Ev12(a))

RATE

59. We have heard a number of explanations of the proposal to set up RATE. The introduction to the draft Bill states that “The Government is committed to establishing RATE as part of its wider review of arms-length bodies”,⁴³ something which the Chief Medical Officer, Sir Liam Donaldson, confirmed. (Q 226)
60. Sir Liam also told us that the EU Tissue Directive pushed in the direction of a merger of the two authorities. He noted synergies between the two, including the relationship between stem cells and potential transplantation of tissues and (potentially) organs, and in terms of the potential of science to draw the work of the two authorities together. (Q 226) This was echoed by the Minister who said that “Currently, we have the HTA, the HFEA and the MHRA as the competent authorities. If we were starting from ground zero ... one would not necessarily think that creating three organisations would be the best way forward.” She also saw overlaps, such as hospitals conducting “work in relation to tissue as well as in relation to IVF, so there are

⁴¹ EU 2004/23/EC

⁴² HFEA/ HTA press release, 20 December 2006

⁴³ Cm 7087, introduction, page viii

opportunities there for possibly joint inspections”, and the elimination of duplication. (Q 489)

61. The Minister also claimed that RATE would provide added flexibility (through the EAP model), increased efficiency and potential cost savings, although she “would not put cost in and of itself above, for example, whether we can be more effective in terms of how we regulate.”⁴⁴ (Q 487) Shirley Harrison acknowledged that some ‘back office functions’ were being “done together already”. (Q 161)
62. When asked, the Minister denied that RATE was, in effect, ‘gold-plating’ the EU Tissue Directive, since it “arose out of looking across government at arm’s length organisations”. However, she acknowledged that “It just so happens that at the same time, alongside that, the EU Directive also clearly indicates that that might be a better model in terms of dealing with that expansive piece of legislation.” (Q 511)
63. We note that in putting forward the case for RATE, the Government presented no research on or assessment of the impact of the current regulatory model before proposals were made to reform it.
64. We received many strong opinions on the formation of RATE. A small minority of witnesses were either neutral about the proposal or saw some potential benefits, largely in terms of efficiency gains and synergies in existing work. However, we were struck by the large majority of witnesses who either expressed concern or were opposed outright to the merger going ahead. We explore this in more detail below.

RATE: efficiency or more bureaucracy?

65. The Institute of Biomedical Science concluded that “The amalgamation of the HFEA and HTA into a single authority will be helpful” to “avoid some areas of duplication and ... any potentially conflicting activities or regulations.” (Ev34)⁴⁵ Both the HFEA and the HTA cited synergies in their work, such as “the regulation of embryonic stem cells”, where “currently the HFEA regulates the creation of the embryos to make cell lines, whilst the HTA regulates activities, like their storage, associated with patient treatment.” However, the HFEA also told us that it had written to the Department of Health in June 2004 outlining the risks of a merger, including: the loss of a dedicated organisation for embryos which in the public’s eye merits separate attention from healthcare in general; loss of expertise from one dedicated organisation; risk of less focussed public accountability; and a loss of reputation and ‘brand image’. Yet the HFEA also recognised that “if a radical change to the HFEA was inevitable” a merger with the HTA carried “least risk”. (Ev11(a) and Ev12(a))
66. However, against this, we had overwhelming evidence against establishing RATE. The Royal College of Obstetricians and Gynaecologists, the British Medical Association (BMA), the Royal Society, the Association of Medical Research Charities (AMRC), the Academy of Medical Sciences, Cancer Research UK, Infertility Network UK, the Royal College of Nursing, the British Fertility Society, the Wellcome Trust, the Medical Research Council

⁴⁴ See also QQ496–502

⁴⁵ See also Ev39

(MRC), and the Royal College of Pathologists all expressed profound reservations about the proposed model.⁴⁶

67. Professor Sir Ian Kennedy, Emeritus Professor of Health Law, Ethics and Policy, School of Public Policy, University College London, and Chairman of the Healthcare Commission, pointed out that “tidiness is not necessarily synonymous with effectiveness; amalgamating them is on its face tidy but it may not be effective.” He added that “in all such amalgamations history tells us that very often you go back to ground zero” and that “such mergers or amalgamations really lose you two years of expertise and administrative skills as you catch up.” (Q 744) Charles Kingsland, Consultant Gynaecologist and Clinical Director of the Hewitt Centre in Liverpool, said that “all I can see is added expense, added bureaucracy, with no benefit to my patients.” (Q 428) Professor Martin Bobrow, Chair of the Academy of Medical Sciences working party on inter-species embryos, thought that “The analysis that puts the two together ... is very superficial” (Q 919), whilst Simon Denegri, Chief Executive of the Association of Medical Research Charities, said that “The business case behind it does not feel very strong.” (Q 920) Dr Tony Calland, Chairman of the Medical Ethics Committee at the BMA said “we do not necessarily feel that if these two bodies were to work effectively RATE would be either cheaper, or, in fact, more effective or less bureaucratic”. (Q 63)

RATE: bringing tissue and embryos together

68. Several witnesses expressed concern that RATE would bring together the regulation of what they saw as two quite different things. For example, Professor Bobrow claimed that “The HTA is essentially concerned entirely with the policing of consent, important but quite trivial in a deep philosophical sense. The HFEA with its remit to look at all aspects of embryology deals with a much wider, more complex range of issues.” (Q 919)
69. In oral evidence, we discussed these concerns. Charles Kingsland agreed that there is a “significant difference” between the two and he could not “be persuaded that [embryos] go along with tissue”. (Q 436) Dr Gillian Lockwood, Medical Director of Midland Fertility Services, spoke for many when she said that the moral status of the embryo “does appear to be unique”:
- “You only have to talk to patients who have frozen embryos before and after their treatment cycle to appreciate what a subtle change happens ... At the point that they have already had a successful baby from their fresh transfer, and they come back two or three years later to use their frozen embryos, those are not just a little bundle of cells any more; that is a brother or sister for their existing IVF baby. As long as that is the mindset that patients have, and I think to a large extent society has, we cannot be quite so cavalier about what exactly it is we are looking at down the microscope.” (Q 433)⁴⁷
70. Dr Mark Hamilton, Chair of the British Fertility Society, and Dr Dave Morroll, Chair of the Association of Clinical Embryologists, agreed but suggested there might be a distinction between embryos to be used for

⁴⁶ See Ev06, Ev07, Ev08, Ev09, Ev23, Ev38, Ev58, Ev59, Ev70, Ev84 and Ev94

⁴⁷ See also Q825 and Q710

treatment and embryos used for research purposes. (QQ 379–381) Dr Simon Fishel, Managing Director of the CARE Fertility Group, argued from a different perspective that tissue and embryos were not of equivalent status since “Tissue is a more elevated structure, a more complex structure, than four cells as a product of conception”. (QQ 430–1)

71. In her letter of 27 June to the Chairman, the Minister claimed that “we take the view that RATE would be established, primarily, to regulate tissue, albeit a range of tissue in various forms.”⁴⁸ This curious approach stands at odds not only with the majority of the evidence we have heard, but also with the Government’s own approach expressed elsewhere.
72. In addition, we also explored the concerns of some witnesses who felt that the name ‘RATE’ itself implies something of a moral equivalence between embryos and other human tissue. For example, the Christian Medical Fellowship, in common with the Church of England Mission and Public Affairs Council, felt that “it is a fundamental mistake of principle to conflate ‘human tissue’—about which ethical concerns are relatively limited and widely agreed—with human embryos, each of whom is a unique being, an embryonic human, worthy of far greater degrees of respect than currently enjoyed, and worthy, we believe, of real protection in law.” (Ev26)⁴⁹ However, Shirley Harrison told us that “there is something to be said for it doing what it says on the tin and making it clear what it is regulating”. (QQ 171–172) Similarly, the Minister confirmed that “we really just wanted to find something so that it was easy for people to see what was on the front of the can”, and said that the Government “were not applying any sort of moral priority to at which point the word came in the title”. (Q 504)

HFEA reputation: domestically and internationally

73. Some witnesses felt strongly that the HFEA’s professional reputation may be lost in any merger. For example, Dr Stephen Minger, Director of the Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Diseases at King’s College London, told us “I have always held this up as the model regulatory environment for doing embryonic stem cell research and embryo research in general. My concern would be that by merging the two entities together you lose that special status of the HFEA, it becomes a watered-down, less tightly regulated and less respectable organisation. It is fair to say that the HFEA is very highly regarded in this country by the general public and certainly by the scientific community, maybe less so by the reproductive medical community.” (Q 598)⁵⁰
74. Both Shirley Harrison and the Minister sought to give examples demonstrating the HFEA’s international reputation. (QQ 146, 485) As we have seen in paragraph 65, the HFEA had already expressed concern to Government that this reputation could be lost if a merger took place.⁵¹ In answer to this charge, the Minister acknowledged that “Nobody wants to jeopardise a good reputation for the sake of a restructuring but I think there are very good sound reasons strategically and operationally for this change to happen.”(Q 497)

⁴⁸ Letter from the Minister to the Chairman, 27 June 2007, see Appendix 8

⁴⁹ See also Ev68, p1

⁵⁰ See also Q757

⁵¹ June 2004 HFEA letter to the Department of Health

75. Others were worried that a switch to RATE could undermine public confidence in this country. Mark Henderson, Science Editor of The Times, pointed out that the name recognition of the HFEA “should not be underestimated”, because “people know what it is” and that “it may perhaps be a little foolish to jettison that.” (Q 300)⁵² Infertility Network UK also warned that the sector “might not benefit from the exclusivity it currently experiences by having more than one regulatory body purely devoted to it.” (Ev58, p2)

Breadth of functions

76. There was also a strong feeling amongst witnesses that there would be a loss of specialist expertise under RATE, particularly because RATE would have such a wide remit. Both the HFEA and the HTA were particularly conscious of their stakeholders’ concerns in this respect. (Ev11(a), para 15, Ev12(a)) Infertility Network UK, the British Association of Counselling and Psychotherapy, and the Royal College of Pathologists all told us that they were worried that their area of work would be “lost” in the new expanded Authority. (QQ 708, 362, 63) The joint submission by the Wellcome Trust and the MRC acknowledged that “RATE will regulate a wide range of sectors, including anatomy, pathology, transplantation, blood transfusion, post mortem research, museums and galleries, fertility treatment, and embryo research”—“highly technical” issues which “raise a uniquely difficult and diverse combination of ethical, scientific and public policy issues.” (Ev09, p2)
77. Likewise, the Royal College of Obstetricians and Gynaecologists reminded us that an HFEA membership of 20 had been criticised for not having sufficient breadth of specialist knowledge. (Ev08, para 1.1) For the BMA, “The fundamental problem” was that RATE “will not have expertise in the areas it is regulating”, and may therefore lack credibility amongst the public, patients, Parliament, or those being regulated. (Ev07, pp1–2)
78. Others argued that the HFEA and the HTA struggled to manage their existing remits. Dr Stephen Minger argued that “The HFEA has been under-resourced for years and over-burdened and in ten years it has expanded”, (Q 608) whilst Professor Sir Richard Gardner, Edward Penley Abraham Research Professor of the Royal Society in the University of Oxford, told us that some of his colleagues working on human embryology complain that the HFEA can be rather slow in deliberating about licenses. (Q 740)
79. Greater concern was expressed about the HTA’s current remit. Cancer Research UK told us that “the HTA is currently overwhelmed by the variety and quantity of its workload”, and that two of its own license applications were “only now being reviewed, some 10 months later.” (Ev94) The Wellcome Trust and MRC claimed that the HTA “ration its resources according to the relative risks of the various activities and sectors it regulates.” This has meant that “Most of the organisations seeking licences for research or display since September 2006 still operate on the basis of deemed licences rather than full HTA licences.” (Ev09) The Royal College of Pathologists, one of the HTA’s key stakeholders, affirmed that the HTA had “struggled to cope with a workload spanning mortuaries, transplantation of solid organs, transplantation of cells, biomedical research, NHS diagnostic

⁵² See also Q602 and Q711

laboratories, anatomy training of medical students, genetic tests and the storage and disposal of diverse human material, from urine to products of conception. We believe that the remit of the HTA has proved to be considerably more complex than was envisaged by those who established it.” (Ev06, pp1–2)

80. The Royal Society felt that RATE would not be able to cope with its workload without an unwieldy “over reliance upon sub-committees, expert advisory panels and working groups.”(Ev59). Meanwhile, the Wellcome Trust and the MRC pointed out that the models and culture of regulation were very different, in that the HFEA “licenses research on an individual project basis, whereas the HTA licenses the storage of tissue for research on the basis of premises.” They asserted that this would make the “transition process particularly challenging”, and would reduce the scope for cost savings. (Ev09, p3)
81. We have already seen the Department of Health, and the HFEA and HTA, draw attention to potential synergies between the authorities. The Minister also expressed the hope that RATE would create opportunities to “streamline ... some of the licensed processes.” (Q 487) Yet for the majority of witnesses who commented, any potential gains were at best neutralised, or at worst heavily outweighed, by the potential drawbacks.
82. There was however one area where some witnesses were willing to accept that synergies could be made—through the merger of ‘back office’ functions. But even here the evidence was mixed. Professor Peter Braude, Head of the Department for Women’s Health, King’s College London, and Chairman of the Scientific Advisory committee of the Royal College of Obstetricians and Gynaecologists, pointed out that back office savings “are probably already taking place. You already have a joint chair, you already have sharing of personnel and various other aspects, they could share premises and there could be interchangeable ideas—why push them together in such a complex, massive body which is going to be more expensive”. (Q 63)⁵³

RATE’s constitution and the Expert Advisory Panel (EAP) model

83. The Minister argued that the EAP model “potentially has an opportunity to be better than what we currently have, which is effectively a board of a limited size, of a limited number of people on it at any one time who bring their own expertise to it. They are doing a good job, I am sure, but we think there is added value to the process through the model we are suggesting.” (Q 496)
84. The Minister, together with Gareth Jones, Director of Scientific Development at the Department of Health, said that the model would provide RATE with flexibility—both in terms of the panels that it set up, and in terms of those who were invited to join them. Gareth Jones said that the model that seemed to work elsewhere was to separate out the expert advice from decision-making. (QQ 498–499)
85. Other witnesses were less convinced. The Royal College of Obstetricians and Gynaecologists argued that there would be “two ‘expert advisory bodies’ reporting to [RATE]; all but in name being the HFEA and the HTA but without any executive function.” They feared that RATE would be “nothing

⁵³ See also Q745

more than an overburdened rubberstamping authority having neither the expertise to fully understand some of the background to the decisions reached by each expert committee, nor the breadth to cover the gigantic range of specialist areas it must cover”. (Ev08, para 1.2.1) The BMA, the Royal Society and the Royal College of Pathologists agreed with much of this. (Ev07, para 3, Ev59, p2, Ev06, para 7)

The Draft Full Regulatory Impact Assessment: costs and savings

86. We also gave some consideration to the costs and possible savings under RATE, as set out in the Government’s Draft Full Regulatory Impact Assessment (RIA).
87. The RIA claimed that “The estimated saving is approximately £700,000 per annum. These savings represent around 10% of operating costs of the HTA and HFEA, which is a useful guide in terms of merged organisations and potential savings.”⁵⁴ However, we had concerns about how robust these assessments were. In oral evidence, Gareth Jones said this was “a rough estimate” and “I would not want to be held to that”. (Q 522) The Wellcome Trust and MRC noted that it would take more than eight years for the savings to offset the costs of the merger. (Ev09)
88. The Minister told us that “the savings have not been independently verified as this is a calculation based on previous mergers and recognising that some of the savings made will be used to improve the effectiveness of the new organisation, for example in setting up and servicing Expert Advisory Panels.”⁵⁵ This implies that the level of savings would be in inverse proportion to the number of EAPs set up. Shirley Harrison told us that “It may be that RATE decides that it needs lots and lots of committees, in which case there may be a larger burden of bureaucracy and more cost.” (Q 192)
89. We found the evidence on the transition costs of RATE also lacked robustness and precision. The RIA estimated transitional costs to be in the range £2m to £6m “depending mainly upon issues of shared accommodation and ultimate location of RATE.”⁵⁶ The Minister told us that “the £2m–£6m figure does significantly depend on the ultimate location of RATE ... In terms of transition costs being at the higher or lower end of the scale, broadly speaking, the more that changes from the existing set up of the HTA and HFEA, the higher the transitional costs.”⁵⁷ The Wellcome Trust and MRC, and the HTA sought confirmation that the costs of the transfer would not be met through licensing income. (Ev09, Ev11(a), p4) This supports our conclusion in paragraph 92 that greater savings, consistency, efficiency and co-operation might be achieved both within and between the two organisations without the creation of RATE.

An alternative to RATE?

90. The Draft Full Regulatory Impact Assessment also set out other options, including “Option 4: Update the 1990 Act but retain the HTA and HFEA.” This commanded more support amongst witnesses than the proposal to

⁵⁴ Draft Full Regulatory Impact Assessment, Cm 6076, pp129–130, paragraph 4.37

⁵⁵ Letter from the Minister to the Chairman, 27 June 2007, see Appendix 8

⁵⁶ Draft Full Regulatory Impact Assessment, Cm 6076, p130, 4.43

⁵⁷ Letter from the Minister to the Chairman, 27 June 2007, see Appendix 8

establish RATE.⁵⁸ The BMA felt that Option 4 had been “dismissed without good reason” and should be given “serious consideration”, through the sharing of back office functions, greater consistency in decision making, closer liaison and communication, and more flexibility in the HFEA’s licensing system, “without the need to merge the two bodies.” (Ev07, p2) In the light of this evidence, we wrote to the Minister on 19 June asking “What level of consideration was given to option 4 ... and what are the reasons for its rejection.”⁵⁹ We were surprised and disappointed by the reply which rehearsed the reasons for RATE rather than giving proper consideration to the alternative.⁶⁰

91. Despite some reservations about the scope of their respective activities and the standard of their regulation, the overwhelming consensus from the evidence we received was that a merger of the two regulators to form RATE would place the positive features of their work at considerable risk. We remain unconvinced by the Government’s arguments that a merger will bring benefits, in terms of savings, synergies, more effective implementation of the EU Tissue Directive, or a more streamlined regulatory process.
92. **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.**

Regulating research and treatment

93. Some witnesses saw the draft Bill as an opportunity to revisit the regulatory approach of the 1990 Act, both in terms of the level of regulation of research and treatment and the relationship between the two.

(1) The relationship between research and treatment

94. Alison Murdoch, Professor of Reproductive Medicine at Newcastle Fertility Centre, argued for a separation of the regulation of research and treatment on the grounds of an internal conflict of interests. She claimed that the HFEA’s recent consultation, *Donation Egg Sharing for Research, Safeguarding Donors 2006* implied that the Authority gives preference to donation for treatment over research, and that “Such a conflict would not arise if the regulation of research and treatment were distinct.” (Ev17)

⁵⁸ Ev08, para 1.2.5 and Q428

⁵⁹ Letter from the Chairman to the Minister, 19 June 2007

⁶⁰ Letter from the Minister to the Chairman, 29 June 2007, see Appendix 8

95. From a different perspective, Comment on Reproductive Ethics (CORE), in common with the Lawyers' Christian Fellowship, argued that a "Conflict of interest is inevitable" because the interests of researchers are in direct competition with best practice for fertility patients—"As fertility treatment moves in the direction of less the research industry clamours for more; more eggs, more embryos in particular." (Ev79, pp2-3, Ev52, p5) However, Shirley Harrison told us she did not see any problem with the HFEA's dual role so long as there is a "proper division of responsibilities and accountability" within its governance framework. (Q 146)
96. Professor Sir Ian Kennedy too felt that to separate the regulation of research and treatment was "an attraction too far because it suggests that you can draw a very clear line between those two activities and that is really rather difficult" since "you are constantly going to be worried about where those borders lie". (Q 752) Others, including Neva Haites, Professor in Medical Genetics at the University of Aberdeen and Chair of the HFEA Scientific and Clinical Advances Group, emphasised the merits of keeping a "very careful eye" on clinics as they introduce new techniques like ICSI and metabolomics. (Q 599)⁶¹

(2) The regulation of research

97. Others argued that the regulatory burden placed on researchers could be eased. For example, Dr Mark Hamilton claimed that there were already robust research regulatory mechanisms in place, for instance through research ethics committees, and that "To piggyback on top of that a need for the regulator, currently HFEA, to be involved in the research assessment process seems to be an unnecessary duplication of effort, and I think the regulator's role should merely be to determine that the research is conducted within the confines of what is the law." (Q 382)⁶²
98. Not everyone agreed. Both Professor Colin Blakemore, Chief Executive Officer of the Medical Research Council, and Roger Brownsword, Professor of Law at King's College London, were concerned about handing the whole process over to local review via research ethics committees because of the "divergence of practice around the country". (QQ 7-8) Professor Martin Bobrow argued that the case for regulation remained because "there is a view that embryos should be treated differently from other constructs." (Q 927)

(3) Regulation of treatment

99. There was a range of opinion on whether there was still a need for close regulation of treatment including the requirement to keep records. A number of witnesses, such as Hugh Whittall, Director of the Nuffield Council on Bioethics, agreed that IVF treatment was now "more or less routine". (Q 5)⁶³ Dr Gillian Lockwood agreed that, in the early days of IVF, the public were concerned that "frightening things were going on", but "Now we know that is not the case, and a lot of the information that we have to collect and send on to the HFEA is of no value at all to patients or to science or to clinicians." (Q 428) She and other clinicians like Simon Fishel were concerned at the

⁶¹ See also QQ922, 600

⁶² See also Q928

⁶³ See also QQ6, 928

“quite remarkable” regulatory burden on staff. (Q 450) Simon Fishel was in favour of a regulatory structure, but he did call for the regulatory process to be streamlined, so that the HFEA only dealt with issues like outcome statistics, personnel review, data on incidents and alerts, public and patient complaints, the maintenance of the register, and “trimmed down” licensing. (Ev85)⁶⁴

100. However, Dr Mark Hamilton argued that there remained value in regulation in terms of “reassuring the public” and “the element of security that it gives those providing the service that they can say we have been inspected by the regulatory authority and we have reached a certain standard that has been approved by the inspection process”. (Q 375) Angela McNab, Chief Executive of the HFEA, warned that a regulator was still required in a sector dominated by private practice, in order to provide “a very clear system for good, professional, evidence-based standards, for ensuring that those are checked, are validated and that where patients have concerns that there is a very clear mechanism for addressing those”. (Q 174) Sir Liam Donaldson told us that “to deregulate in this field would be a bit of a disaster, and the reason I say that is that I think we have a duty to the welfare of patients.” (Q 230)
101. Others questioned whether IVF could really be considered ‘routine’. Professor Sir Richard Gardner pointed out that “Clinical practice in this area does not gradually become routine” since “people are forever looking at new ways to assess the developing embryos”. (Q 753) He also argued that adverse prenatal experiences may first affect people later in life, and that there was therefore an ongoing case for keeping records. (QQ 755–756)⁶⁵
102. Several witnesses also touched on the regulatory overlap between the HFEA and other regulators outside the field of embryology. Dr Gillian Lockwood told us about the degree of overlap with other regulators, such as the Healthcare Commission “to look after the patient side of things” and the British Standards Institute “which manages our ISO accreditation and the quality management system which is part of the EU Tissue Directive”. (Q 453)⁶⁶ Professor Sir Ian Kennedy, Chairman of the Healthcare Commission, confirmed that “there is duplication”, and acknowledged that “we are from time to time tripping over each other.” (QQ 761–762)⁶⁷ Charles Kingsland agreed that, from the point of view of treatment, the HFEA had been superseded by other regulatory bodies within the NHS, (Q 459) but Professor Sir Richard Gardner was keen to see the HFEA retain its regulatory role. (Q 754) Dr Dave Morroll pointed out to the Committee that the laboratory elements of assisted conception would have to be inspected in any case to ensure they complied with the technical elements of the EU Tissue Directive. (Q 373)
103. The Minister said the Government “still feel there is a role for regulation” of IVF, both because it creates a “confident atmosphere” for treatment to take place, and because “To dismantle that could potentially undermine the confidence of the public in this particular area.” (QQ 485, 512–521) She did however concede that “there are ways to look at a lighter touch approach and

⁶⁴ See also Q924

⁶⁵ See also Q757 and Ev85, p1

⁶⁶ See also QQ364–5, 441, 450, 453, 459 and Ev85

⁶⁷ See also Ev17, p1

to see where, potentially, in the future, some aspects of regulation may not be necessary”, for instance to deal with concerns about time delays, or organisations that have demonstrated their quality and have suffered no complaints against them. She argued that this “could be revised as part of the practice of regulation that we currently have”, although the Committee pointed out that, under the draft Bill, the fundamental requirement for a treatment licence could not be relaxed. (QQ 512, 514)

(4) The overall regulatory structure

104. In respect of both research and treatment, others, such as the Church and Society Council of the Church of Scotland, and the Lawyers Christian Fellowship, argued that strict regulation “continues to be essential” under a “strong independent regulatory authority”. (Ev52, p5, Ev97, p3)

Conclusion

105. We have listened carefully to arguments about the regulatory structure, in both the research and treatment fields. We would not wish to see the Government or the regulator involved when responsibility can reasonably and safely be devolved, either to researchers or clinicians. Yet we acknowledge that the special status of the embryo means regulation of both research and treatment continues to be appropriate and desirable. In addition, we recognise that regulation of IVF treatment provides assurance and protection to patients. **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.** We have considered claims that the regulation of treatment and research should be separated, but we are persuaded by the evidence we have received that the relationship between the two fields is so close and interdependent as to make this impracticable.

Reform of the Human Tissue Act 2004

106. Early in our inquiry, the Royal College of Pathologists put to us a strong case for revisions to the Human Tissue Act 2004 (the 2004 Act) on the basis that the Act was drafted in a way that put unnecessary and unintended burdens on the stakeholders. (Ev06) They told us that “The 2004 Act was drafted with post mortem samples in mind. But the Act defines human tissue as anything containing human cells (with certain specific exceptions). Consequently, legislation designed to protect the hearts and brains of the deceased also applies to urine, faeces, saliva and pus from living patients, since all of these contain human cells.” This means that the Act applies to almost all specimens from the living which pass through NHS laboratories—approximately 200,000,000 samples each year. In contrast, fewer than 150,000 post mortem examinations take place each year. A number of witnesses, including Lord Patel, Professor Martin Bobrow and Cancer Research UK agreed that the Act created unnecessary burdens. (QQ 931–932, Ev94).

107. In particular, the Royal College drew our attention to a number of specific problems they found with the operation of the 2004 Act (see Ev06). They also told us that when they made representations to the Department of Health for amendments to the 2004 Act, they were “told, in effect, that no such problems existed, and that no such changes could be expected.” (Ev06) Dr Suzannah Lishman, Assistant Registrar, Royal College of Pathologists, was concerned that “the amendments to the Act that were suggested have been completely ignored and that this draft Bill completely ignores everything to do with the Human Tissue Act and concentrates on the embryology side of things.” (Q 66)
108. The HTA argued that, though it may be too early to make judgements on its regulatory work, the draft Bill provided an opportunity to “identify parts of the current Human Tissue Act which may benefit from change or clarification.” While the HTA’s members concluded that its understanding of the current legislation needed to mature before it could recommend specific changes, the HTA did suggest the Authority should have some flexibility in defining “relevant material”, and that “an element of discretion” should be allowed in order to extend the list of ‘qualifying relationships’ in section 27 of the Act. (Ev11(a), p5)
109. The regulation of tissue is a devolved matter in Scotland. The Scottish Parliament passed the Human Tissue (Scotland) Act 2006, which legislated only in respect of tissue removed after death. In addition, the Act provides that tissue blocks and slides become the property of the hospital, which would then be free to conduct any ethically approved research in the future. Both these policies reflected the recommendation of the *Independent Committee of Inquiry into the Retention of Organs at Post-Mortem*.⁶⁸ The Act also provided for post-mortem samples to be kept in perpetuity in a case of Sudden Infant Death Syndrome. Baroness Kennedy’s report⁶⁹ on the investigation of unexpected death in infancy had come to a similar conclusion. Yet all of these practices are illegal in England and Wales under the 2004 Human Tissue Act.
110. The Royal College of Pathologists said that to legislate only in respect of tissue removed after death was “logical”, given the very different attitudes to the body of the deceased, as compared to the organs, tumours or faeces of living patients, and called on the Westminster Parliament to follow suit. (Ev 06) They told us that other possible (but less effective) reforms might be to redefine ‘relevant material’ so as to exclude blood, urine, faeces etc, or, as a minimum remedy, to give the HTA or the Secretary of State power to alter the range of material covered under the 2004 Act.
111. Professor Neva Haites, from the University of Aberdeen, who has direct experience of the Scottish Act claimed that in Scotland “we have a much less bureaucratic process” that is “working very effectively” with the confidence of researchers and pathologists. (Q 596) She added that research using spare tissue after surgery “has virtually come to a standstill in England because of an inability to know how to actually use the current rules, whereas in Scotland providing you have full consent and ethical committee approval there is no issue.” (Q 611)

⁶⁸ Independent Review Group. Retention of organs at post mortem. Final report. Edinburgh: The Stationery Office, 2003.

⁶⁹ Sudden unexpected death in infancy. A report from the working group of the Royal College of Paediatrics and Child Health and the Royal College of Pathologists. September 2004.

112. In addition, concern was also expressed about HTA storage licences. The Royal College of Pathologists said that the size of these fees had come as an “unwelcome surprise” for many hospitals, faced with a choice of paying for storage or destroying samples, thereby creating “a financial stimulus to the destruction of appropriately consented samples”. Lord Patel agreed that it would be “a tragedy” if specimens were lost in this way. (Q 931)
113. In response to concerns about the 2004 Act, the Minister told us that, since these issues were only aired recently, “we are not convinced of the need for further amendments.” In the context of the Scottish approach to the retention of tissue samples and Sudden Infant Death Syndrome tissue sampling, she said that “unless there is a criminal prosecution, to keep these tissues indefinitely does not seem to be an appropriate thing to do, and certainly not without the permission of the families concerned.” (QQ 506–507) We disagree with both statements. However, Sir Liam Donaldson assured us this could be looked at if there was a strong and persuasive case for amending the law, and both he and the Minister said that the Government would be prepared to listen to any recommendations that the Committee made. (QQ 272–274, 506)
114. Whilst we did not receive a large quantity of evidence on this issue, what we did receive we found very persuasive. The majority of witnesses who did express an opinion agreed that the 2004 Human Tissue Act needs to be revised. We are also mindful of the Royal College of Pathologists’ concerns that issues in relation to the Human Tissue Authority could get lost amidst all the other proposals in the draft Bill. The Government’s argument that it is too soon to amend the Act does not stand up to scrutiny. If the law needs amending, as the Committee believes it does, it should be done as quickly as possible. The Committee also notes the weight of evidence suggesting that the Human Tissue (Scotland) Act has achieved a far better result, in particular in terms of legislating only for tissue removed after death, the retention of tissue blocks and slides, and the retention of post-mortem samples in a case of Sudden Infant Death Syndrome. We reject the Government’s conclusion that it is too soon to amend legislation as it applies to England and Wales. **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.**

Embryo transfer in treatment

115. We heard evidence from a number of witnesses about the problems of multiple embryo transfer during fertility treatment. There was a large degree of consensus on this issue, and the British Fertility Society’s submission was typical:
- “Good clinical practice should be encouraged subject to guidance from appropriate professional bodies ... If outcome data suggest to the regulator through the inspection process that clinical or laboratory practice is suboptimal then those providing services should be called to account.” (Ev23)⁷⁰
116. The Royal College of Nursing referred to the Multiple Births and Single Embryo Transfer (MBSET) stakeholders consensus statement, which said

⁷⁰ See also QQ140, 478, 592, 875 and Ev06, Ev07, Ev12(a), Ev23, Ev36, Ev38, Ev51, Ev57 and Ev58

that “The only way to reduce multiple birth rates after IVF is to transfer only one embryo to those women at most risk of having twins.” (Ev38, para 11.1) The National Infertility Awareness Campaign, also a signatory to the consensus statement, argued that “inadequate implementation of the NICE Guideline to Fertility (2004)” whereby patients are entitled to three full cycles of IVF treatment, meant that patients were unwilling to risk Single Embryo Transfer “in what could be their only state funded IVF cycle”. (Ev57) Dr Gillian Lockwood told the Committee that “until we are in a situation where we can hand on heart say that the chance of getting pregnant at all is the same ... it will be terribly difficult to persuade couples ... to have just one transferred.” (Q 478)

117. Whilst noting widespread concern about this issue, we acknowledge the weight of evidence that the draft Bill is not an appropriate vehicle with which to seek to solve the problem. This should be left to clinicians working under appropriate guidelines from the regulator.

Paying for the regulator

118. Aside from the cost and potential savings of the proposal to create RATE (paragraphs 86 to 89), the Committee heard views on a range of funding questions, including; the question of whether the regulator should be funded by licence fees, grant-in-aid, or a combination of both; the financial burden placed on researchers, clinics and patients; and whether there was any evidence of a conflict of interest or cross-subsidy.

Paying for regulation

119. The Minister told us that that it remained Government policy “that where we are regulating, the cost of regulation should pay for itself through the form of fees. At the present time we obviously provide grant in aid for advice and information, so that those areas of the role of the organisation are distinct.” (Q 522) The HFEA told us that they saw no reason why this model should not continue. (Ev12(a))⁷¹ However, the Christian Medical Fellowship felt that an increase in funding by grant-in-aid was needed to avoid a conflict of interest, whereby the regulator has “a positive incentive to issue licences for fees in order to maintain its own existence.” (Ev26, p4)
120. Others favoured an increase in funding by grant-in-aid from the point of view of fairness to patients. Dr Mark Hamilton, echoing the comments of Dr Simon Fishel and Hugh Whittall, as well as Sheila Pike from Sheffield Teaching Hospitals NHS Trust, and Kate Grieve from University Hospitals Coventry and Warwickshire NHS Trust, told the Committee that “infertility is not a lifestyle choice. Patients who have infertility have a medical condition; they do not wish to have it and the consequences of that condition have far-reaching medical, psychological and social consequences. It seems unfair to me that the infertile are singled out in this way to pay substantial amounts of money for the purpose of the regulation of treatment which they very much deserve.” (Q 386)⁷² While we note that a number of witnesses called for an increase in funding by grant-in-aid, we do not in this report seek to challenge’s the Government’s position that the cost of regulation should be met by a mixture of licence fees and grant-in-aid.

⁷¹ See also QQ746–747

⁷² See also Q438, Q20, Ev22, p1

121. We also received some evidence expressing concern at the overall funding balance within RATE and the risks of cross-subsidy and conflicts of interest within RATE, particularly the potential for “one sector underwriting the regulatory activities of another.” (Ev23, p4)⁷³ We note these concerns, but given our recommendation against RATE we have not covered these issues in our Report in depth. We did hear evidence about research licence and treatment fees charged by the regulator which are as relevant to the current structure as they are to RATE and we deal with these below.

Research licence fees

122. Several witnesses expressed concern about the requirement for and the cost of HFEA licence fees to undertake research in this area and the imbalance this created with other areas of research. For example, Professor Alison Murdoch told us she thought the requirement for an HFEA licence was unreasonable, and caused “harmful delay and cost.” (Ev17, p4) Professor Peter Braude and Professor Sir Ian Kennedy admitted that research licence fees were “anomalous” in comparison to other biomedical research. (QQ 89, 747) Professor Braude further told us that the fee “would get passed to the Medical Research Council or whoever is funding it but usually charities or own accounts for research and it seems to be an inhibitor to doing it, I am not sure why we have to.” (Q 91) Professor Blakemore added that “the cost in the end has to be borne by a purse, a public purse, a charity purse or whatever, and I do not think it would be unreasonable to ask the Government to be covering these costs of running these services well and separately through researchers.” (Q 23)
123. However, the Biotechnology and Biological Sciences Research Council, in common with Mark Henderson, Science Editor of The Times, told us that “Government funded research grant application mechanisms now permit the costs of licences to be included in the grant proposal and so if a project was successful, the majority of the cost of a licence could be met through that research grant.” (Ev39, p2, QQ 308, 610) Hugh Whittall felt that the charging of a fee (whether for research or treatment) was appropriate as a barrier to entry, and to provide a “measure of entitlement” for those paying fees. (Q 20) **We recommend that Research Council grants should include the cost of research licences.**

Treatment fees

124. We also heard much evidence on HFEA fees charged for IVF treatment. Dr Mark Hamilton, Dr Gillian Lockwood, Dr Simon Fishel and Infertility Network UK told us that patients and clinicians perceive the £104 fee as a “very regressive” “straightforward fertility tax”, which “given the current lack of NHS funding for fertility treatment”, most patients “have no choice but to pay.” (QQ 365, 440, 448 and Ev58, p3) Dr Lockwood told us that her own clinic pays £150,000 “fertility tax” per year. (Q 440)
125. We were particularly interested to know whether there was any evidence of patients being exploited through additional or inflated fees [in the private or public sectors]. Charles Kingsland, an NHS consultant, told us that “there are an awful lot of treatments that are in theory beneficial but have never stood the rigour of scientific evaluation ... These are the treatments that can

⁷³ See also QQ183–192

be very expensive and whereas they may not do any harm to the patient ... they may not be doing any good either. What we have in this particular area of medicine are patients who are very vulnerable and can be influenced by non-evidence-based medicine.” (Q 445) Sheila Pike and Kate Grieve claimed that “The policy of leaving treatment fees to be decided in relation to market forces has led to unjustifiably high prices for IVF in some centres and is contributing to the disturbing phenomenon of fertility tourism.” (Ev22, p1) However, Dr Simon Fishel, who currently works in the private sector, said that he knew of no evidence of exploitation. (Q 442)

126. The HFEA told us “We would like to see an explicit provision in the Bill requiring assisted conception clinics to provide patients with fully costed treatment plans and to have in place a proper patient complaint system. At present, the HFEA is limited in what it can do to protect patients who may be at risk of exploitation by some private sector clinics. Explicit requirements on clinics coupled with a clear function for the regulator relating to safeguarding the interest of patients, could make it easier for these concerns to be addressed.” (Ev12(a), Appendix A)
127. We support the HFEA’s general approach in this area. **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.**

NICE guidelines

128. We have also heard from witnesses concerned about funding issues in fertility treatment beyond the regulator, particularly suggesting that Primary Care Trusts either were not implementing NICE guidance⁷⁴ or were implementing them inconsistently. Dr Mark Hamilton complained about the “scandal which is the national failure to implement the NICE guidance around the management of the infertile which, one is led to believe, is purely a matter of resource allocation.” (Q 365) Dr Tony Calland told us that “there is, in reality, very much a postcode lottery about the availability of IVF services.” He said that patients may not have NICE guidelines implemented in their area and noted that “it does not work in the patients’ interests.” (Q 89) Charles Kingsland, an NHS consultant, claimed that in the NHS at least, the cost to the NHS of IVF treatment is likely to be between £2,600 and £3,300 for a cycle of treatment which is “relatively cheap if you compare it with other well-established medical conditions.” (Q 442)
129. We are concerned by the evidence we have heard that NICE guidance is not being implemented consistently across much of the country, thereby delivering unequal access to the public provision of fertility treatment services in England and Wales. **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.**

⁷⁴ Fertility: assessment and treatment for people with fertility problems, NICE Clinical Guidance 11, February 2004

CHAPTER 6: PART 2 OF THE DRAFT BILL—AMENDMENTS OF HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Definitions

Introduction

130. Part 2 of the draft Bill contains a series of key definitions intended to define the parameters of both the regulator’s remit and acceptable practice in embryology research and fertility treatment. These functional definitions are fundamental to the Government’s approach to the regulatory architecture in the draft Bill. Similarly, our approach to definitions is guided by our approach to regulatory design set out in Chapter 4. Getting the definitions right is therefore a key challenge, summed up by Roger Brownsword, Professor of Law at King’s College London: “you want the best of all possible worlds and people who want flexibility also want calculability and certainty in knowing where they stand as well as accountability—it is not straightforward.” (Q 16)
131. Definitions can be drafted more or less restrictively, depending on whether the aim is to provide flexibility or legal certainty. Some witnesses favoured a more restrictive approach with a high degree of parliamentary control and less leeway for the regulator in terms of its remit and its scope for interpretation. (Ev79, para 3.2) Others, however, have argued that this approach places unacceptable fetters on the development of scientific research. (Ev17, para 3.2)
132. We have already recommended that the draft Bill should embrace the principle of ‘devolved regulation’. This would require definitions to be broad enough to allow the regulator appropriate flexibility in the exercise of its regulatory functions, yet certain enough that both the regulator and the scientific community can be reasonably confident about the legal boundaries of their actions. We think this approach will be particularly useful where the future direction of research or treatment is unclear, so that the regulator has greater scope for granting or refusing licences for activities which had not been foreseen at the time the legislation was passed. We also favour a strong ethical framework, to be provided by Parliament, within which the regulator can operate.⁷⁵
133. The draft Bill (clause 14) sets out a series of very broad definitions of embryos and gametes, which effectively set the scope of the regulator’s authority. These concepts are then refined in a tiered approach for different purposes: there are “permitted embryos” and “permitted eggs and sperm”, which are the only sort which may be placed in a woman; and “inter-species embryos” which are marked out for more stringent regulation. Professor Brownsword had twofold concerns about the general approach in the draft Bill: first, they did not map to scientific understandings of the defined concepts (he considered it important that definitions were understood by researchers and clinicians); and, second, the tiered approach was overly complex and apt to confuse. (Q 29) However, Hugh Whittall, Director of the Nuffield Council on Bioethics, thought the tiered approach

⁷⁵ This approach was supported by witnesses: QQ169, 619–620, 622, 640, Ev12(a), paras 3, 4, 10 and 43

was helpful in defining what did and did not fall within the definitions. He acknowledged, however, that this approach introduced complexity which could be problematic for practitioners unless the regulator could find a way to clearly present their effects. (Q 32) The HFEA and the HTA favoured the pragmatic, functional definitions in the draft Bill. (QQ 195, 198)

Definitions in clauses 14 and 15

134. Clause 14 amends the definitions of “embryo”, “eggs”, “sperm” and “gametes”, the practical effect of which would be to amend the existing definition of “embryo” so that the 1990 Act would apply to all live, human embryos, regardless of their manner of creation.⁷⁶ Therefore, “embryo” will mean a live human embryo, including an egg that is in the process of fertilisation or which is undergoing any other process capable of resulting in an embryo.
135. Some witnesses objected that the definition of “embryo” made no scientific sense or that it should be clarified. For example, Dr Dave Morroll, Chair of the Association of Clinical Embryologists, stated a preference for a distinction to be made between “eggs in the process of fertilisation and embryos that have undergone cleavage”. (Q 391)⁷⁷ However, many witnesses supported the revised definition of “embryo”.⁷⁸ Dr Mark Hamilton, Chair of the British Fertility Society, acknowledged that the end use of the entity was the most important aspect for regulatory purposes. (QQ 391, 393)
136. Clause 14 includes in the definition of “eggs”, “sperm” and “gametes”, not only mature eggs and sperm, but also “immature gametogenic cells, such as primary oocytes, and spermatocytes”.⁷⁹ “Eggs” will include “cells of the female germ line at any stage of maturity”, and “sperm” will include “cells of the male germ line at any stage of maturity” (clause 14(4)). Some concern was raised about the breadth of these definitions⁸⁰ and several witnesses argued that this would bring within the scope of regulation under the 1990 Act basic science projects on the development of germ cells which are not at present regulated by the HFEA and which, subject to consent, do not currently require an HTA licence.⁸¹
137. Clause 15 defines “nucleus” and clarifies that the definition includes the pronucleus. As with the other definitions, some witnesses welcomed this clarification while others objected that it made no scientific sense and the intention underlying the definition needed to be clarified.⁸²
138. While we note the calls for clarification of some of these definitions, we agree with the HFEA 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 ... It is almost impossible to arrive at a scientifically

⁷⁶ Explanatory Notes, para 45, White Paper, para 2.11

⁷⁷ See also Ev06, para 6, Ev77, para 7(a), Ev85(a), para 1, Q465

⁷⁸ See Ev12, para 13, Ev12(a), para 21, Ev28, comments on clauses 14 and 15, Ev41, question 7(a) and (b), QQ395, 770–771

⁷⁹ Explanatory Notes, para 49

⁸⁰ Ev23, para D, Ev28, comments on clauses 14 and 15, Ev08, para 1.13, Ev41, answer to Q7(a) & (b), Q396

⁸¹ Ev08, para 1.13, Ev09(a), answer to Q2, Ev06, para 6, Ev23, para D

⁸² See Ev12(a), para 21, Ev28, comments on clauses 14 and 15 and Ev06, para 6

acceptable definition of an embryo, for example, that avoids creating unintended exceptions or anomalies.”(Ev12(a), para 22) **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.**

Secretary of State’s power to extend definitions

139. Clause 14(5) provides that the Secretary of State may make regulations to extend in prescribed circumstances the definitions of “embryo”, “eggs”, “sperm” and “gametes”, although he may not extend the definition to include anything containing non-human DNA. There is also a limited power in clause 16(5) for regulations to provide that eggs and embryos which have been treated to prevent the transmission of serious mitochondrial disease may be “permitted” (we comment on the provisions in clause 16 in more detail in paragraphs 179 to 189).
140. Some witnesses objected that developments in this particularly sensitive field of science should be a matter for Parliament alone and a regulation-making power should not be given to the Secretary of State.⁸³ Conversely, one witness argued that all such decisions should be left to the regulator. (Ev64, para 4.2) A significant number of witnesses, however, supported the approach in the draft Bill.⁸⁴ The House of Lords Delegated Powers and Regulatory Reform Committee advised us that:
- “... the use of an affirmative procedure order to bring additional matters within the scope of an Act is well established. Since the power in this case may be used only in the light of developments in science or medicine, and cannot be used to apply the Act to items which could not reasonably be described as embryos, eggs, sperm or gametes, we do not consider the approach inappropriate.”⁸⁵
141. We note this advice and we support the provisions in clause 14(5) which provide a degree of flexibility for the regulatory regime.

Inter-species embryos

142. Clause 17 proposes a new section 4A to be inserted into the 1990 Act to introduce prohibitions in connection with genetic material not of human origin.⁸⁶ Clause 17(2) defines “inter-species embryo”. This has been one of the most contentious issues in our inquiry and one in which many witnesses had opposing, deeply-held views. The net effect of new section 4A is that an inter-species embryo may only be created, kept and used under licence, subject to the 14-day rule (see below) and may not be placed either in a woman or in an animal. There is no question of an inter-species embryo being allowed to develop past the 14-day stage. We have set out the main provisions below:

⁸³ Ev25, para 7(b), Ev28, comments on clauses 14, Ev40, para 3.3, Ev52, para 7(b), Ev55, para 7(b), Ev62, paras 7(b)(ii) and (iii), Ev92, heading: Definitions

⁸⁴ Ev38, para 5, Ev12, para 13, Ev12(a), para 23, Ev39, para 11, Ev41, answer to Q7(a) and (b), Ev59, para 7(a), Ev84, para 2, QQ16, 32, 197, 392, 946–948

⁸⁵ Memorandum dated 13 June 2007, see Appendix 7

⁸⁶ In this Report we refer to these new provisions by reference to their new section number (as inserted in the 1990 Act).

- (1) Section 4A(1) provides that only a human embryo and human gametes may be placed in a woman. Any other types of embryo or gametes, including inter-species embryos, are specifically prohibited from being placed in a woman.
- (2) Section 4A(2) prohibits the mixing of human and animal gametes and the creation, keeping or use of inter-species embryos except in pursuance of a licence.
- (3) Section 4A(3) provides that an inter-species embryo, created under licence, may not be kept or used after the earliest of:
 - (a) the appearance of the primitive streak;
 - (b) 14 days from the beginning of the process of creation; or
 - (c) half the gestation or incubation period for any species whose DNA is contained in the embryo.

(This provision is sometimes referred to as the ‘14-day rule’, 14 days being the longest possible period that such an entity may be kept and used.)

- (4) Section 4A(4) provides that an inter-species embryo may not be placed in an animal.
- (5) Section 4A(5) defines an inter-species embryo as follows:
 - (a) an embryo created by using human gametes and the gametes of an animal, (‘true’ hybrid)
 - (b) an embryo created by replacing the nucleus of an animal egg or a cell derived from an animal embryo with a human cell or the nucleus of a human cell (cytoplasmic hybrid or cybrid)
 - (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal (human transgenic embryo)
 - (d) a human embryo that has been altered by the introduction of one or more animal cells (human-animal chimera) or
 - (e) any other embryo that contains both—
 - (i) any haploid set of human chromosomes, and
 - (ii) any haploid set of animal chromosomes or any other sequence of nuclear or mitochondrial DNA of an animal (the ‘catch-all’ provision).

143. In line with the definitions in clause 14, section 4A(7) states that “embryo” means a live embryo, including an egg in the process of fertilisation, and section 4A(8) defines eggs, sperm and gametes as live eggs or sperm, including cells of the female or male germ line at any stage of maturity.

144. The approach to the definition of inter-species embryos is different from the approach to definitions in clauses 14 and 15. Rather than a single, wide definition the Government has chosen to list the known methods of creating the entity in question (subsections (a) to (d)) and to add the ‘catch-all’ in subsection (e).

General points on inter-species embryos

145. We have received a significant quantity of evidence on inter-species embryos and we recognise the strongly-held views. It is largely the case that those in favour of the inter-species embryo provisions support the scientific potential of such research, and those against see them as ethically ambiguous or wrong. We have sought in our deliberations to respect these views and find a balanced approach.
146. We heard from many witnesses who were opposed entirely to the provisions in clause 17. Some noted that inter-species entities were banned in other countries.⁸⁷ Most witnesses who opposed inter-species embryos did so on one (or more) of the following grounds: the moral status of the embryo; crossing the species barrier; and the lack of scientific merit of such research.
147. Most of those who attended the evening forum were opposed to inter-species embryos on the basis of the moral status of the embryo. For example, Paul Tully, General Secretary of the Society for the Protection of Unborn Children (SPUC), argued that it was precisely because the moral status of the resulting entity was not known that his organisation objected to the creation of ‘true’ hybrids. The Rt Revd Dr Lee Rayfield, Bishop of Swindon, and representative of the Church of England Mission and Public Affairs Council, thought that the Church of England would probably view them as genetically disabled human beings. Dr Donald Bruce, Director of the Church of Scotland Science, Religion and Technology Project, thought that the fact of its non-viability may itself be morally objectionable.⁸⁸
148. Søren Holm, Professorial Fellow on Bioethics at Cardiff Law School, and Professor of Medical Ethics at the University of Oslo, told us that, in his view, all inter-species embryos were equally problematic for the reason that they cross the species boundary. This view was supported by many others.⁸⁹ For example, Donald Fleming told us “This is unethical research: the more the species barrier is crossed, the less clear cut will become the definition of being human. The mixing of human and animal would challenge the very concept of being entirely human. The unnatural entities created will be less human than fully human embryos and natural boundaries will be violated.” (Ev1, para 4b)
149. Reservations were also expressed that the scientific rationale for the creation and use of interspecies embryos was flawed. Several witnesses thought that an inter-species embryo could never form a suitable model for human disease and treatment because of its mixed genes and that its creation and use should be prohibited on the basis that it could perform no scientifically useful function.⁹⁰
150. However, we also heard from a large number of witnesses who supported the licensing of inter-species embryos.⁹¹ Some witnesses argued that the creation

⁸⁷ Inter-species embryos are banned in countries including France, Germany, Italy, the Netherlands, Belgium and Canada—see for example (Ev01, para 5), Evening Forum Report, Appendix 5

⁸⁸ Evening Forum Report, Appendix 5

⁸⁹ Ev02, para 2, Ev03, para 3, Ev13, para 6, Ev15, para 8, Ev18, para 2, Ev20, Ev22, para 2, Ev24, para 3, Ev25, para 8, Ev26, para 11, Ev42, para 23, Ev52, para 8, Ev55, para 8, Ev61, paras 3–4, Ev62, para 8(h)(vi), Ev65, para 4, Ev66, paras 2.1 and 2.7, Ev92, para 7

⁹⁰ Ev01, para 3, Ev03, para 3, Ev13, para 6, Ev45, Summary para 2 & para 29, Ev52, Summary para 3, Ev66, para 2.1, Ev79, paras 4.1–4.5

⁹¹ Ev59, para 8, Ev38, paras 6–7, Ev09 Appendix A, paras 12–17, Ev09, answer to Q8, Ev12(a), para 24, Ev23, para E, Ev28, comment on clause 17, Ev39, para 12, Ev40, para 4, Ev41, para 2 and answer to Q8, Ev48, para 3, Ev49, para 6.1, Ev51, para 8, Ev59, para 2 and answer to Q8, Ev60, para 4.1, Ev64, para 5.1, Ev67, para 3, Ev70, Appendix 1, para 8, Ev71, para 2, Ev77, para 8, Ev90, para 6, Ev94, Part 2, QQ19, 37, 782, 951

and use of inter-species embryos are essential, both to compensate for the shortage of human eggs and embryos donated for research and to avoid the potential harm caused to the women and families who donate them.⁹² This claim goes hand in hand with the argument that genuinely useful scientific developments are likely to arise out of research using inter-species embryos. (Q 782)

151. Furthermore, Professor Colin Blakemore, Chief Executive Officer of the Medical Research Council, argued that there was no evidence of the public revulsion asserted by some. He highlighted a recent survey in which 70% of the public were found to be supportive of inter-species embryos and noted that there has been no real outcry in the press against the practice. (Q 39) This view was echoed by Mr Fergus Walsh, Medical Correspondent for the BBC, who was “not sure the public is really staying up late worrying about it”. (Q 331)

Government policy

152. The Government’s changes in policy in this area have not been helpful in trying to find the right balance. In its December 2006 White Paper, the Government stated that the creation of inter-species embryos *in vitro* would be prohibited, but that a regulation-making power would allow Parliament to agree exceptions to that prohibition for research purposes.⁹³ This is the policy reflected in the text of the draft Bill.
153. Following the White Paper, the Commons Science and Technology Select Committee published a report recommending that legislation should be permissive and provide that “in general, the creation of all types of human-animal chimera or hybrid embryos should be allowed for research purposes” under licence by the regulator. The intention was that ‘pure hybrids’ should be included in the licensing regime.⁹⁴
154. On publication of the draft Bill in May 2007, the Government announced its intention to accept, in part, the Science and Technology Committee’s recommendation and allow in legislation, under licence, the categories of inter-species embryo described in section 4A(5)(b) to (d).⁹⁵ ‘True’ hybrids and entities falling within the ‘catch-all’ provision would remain proscribed unless permitted by regulations made by the Secretary of State.⁹⁶ The Government confirmed this policy to us in a letter dated 12 June (see Appendix 9). Given the time available for our inquiry, the level of uncertainty about the Government’s position has been extremely unhelpful.
155. From the evidence received, we have identified three particular issues which we cover in turn below. The first issue relates to the rationale for treating ‘true’ hybrids differently from those entities falling within categories (b) to (d). The second issue arises from the ‘catch-all’ provision. Related to this is a third issue of the regulatory ‘gap’ between clause 17(2) of the draft Bill and the Animals (Scientific Procedures) Act 1986.

⁹² Q782, Ev13, para 6, Ev48, para 5, Ev49, para 5.1, Ev70, Appendix 1, para 8, Ev92, para 7

⁹³ White Paper, para 2.85

⁹⁴ Government proposals for the regulation of hybrid and chimera embryos, March 2007, HC 272-I. The Report also recommended that use of inter-species embryos for research purposes would be subject to the 14-day rule and there would be a ban on placing such embryos in a woman (paras 88, 90, 93 and 94)

⁹⁵ Introduction to the draft Bill, paras 1.12–1.13

⁹⁶ Under clause 38(5), such regulations would require the affirmative procedure

Section 4A(5)(a): 'true' hybrids

156. A significant number of witnesses told us they did not understand in principle why a distinction is being made between 'true' hybrids and other categories of inter-species embryos.⁹⁷ For example, Dr Vivienne Nathanson, Director of Professional Activities at the British Medical Association (BMA) stated that she could "see no sense" in the exclusion of true hybrids. (Q 95) On a different basis, Professor Holm argued that there is no qualitative difference to be found between 'true' hybrids and other inter-species embryos, because the creation of all types of inter-species embryo is equally objectionable on ethical grounds. (Q 854)
157. We asked the Chief Medical Officer, Sir Liam Donaldson, to clarify the distinction between a cytoplasmic hybrid and a 'true' hybrid. He told us "The process involved and the resulting entity is very different in character to the first. I am surprised that you cannot see that. I think the outside world would see a big distinction." (Q 249) He also sought to explain the rationale for treating 'true' hybrids separately from other types of inter-species embryos. He argued that there was no clear scientific benefit to be derived from 'true' hybrids and that this would constitute a "step too far as far as the public are concerned". (Q 244) He further argued that scientific development should not forge ahead of public opinion to this extent in the absence of strong, scientific imperatives. (Q 244) Surprisingly, Sir Liam Donaldson gave no evidence of how he had ascertained the state of public opinion.
158. We put to the Minister the argument presented to us, that once researchers have "crossed the species barrier" there is no valid distinction to be made between an entity that is 99% human and an entity that is only 50% human and that it would be nonsensical to accord greater protection to the latter via a ban on research use. The Minister rejected this argument. (Q 555) She told us that the decision to ban 'true' hybrids for the time being was pragmatic, on the basis that there was currently no call for research using 'true' hybrids. She thought that Parliament should be given the opportunity to discuss the issue at a later date, rather than now permitting on the face of the draft Bill research in an area which was, as yet, largely unknown. (QQ 556, 566) She also argued that public opinion was a concern and that, although policy-making should not be a hostage to public opinion, it was nevertheless important to give reassurance that there was a purpose to the research which was being allowed. (Q 567) We are not persuaded by this evidence.
159. In addition, several witnesses noted the so-called 'hamster test', in which human sperm are mixed with hamster eggs to test the health and motility of the human sperm. This is well established and explicitly endorsed in paragraph 6 of Schedule 2 to the draft Bill.⁹⁸ They argued that, if the hamster test is allowed, there should be no problem allowing other types of inter-species entity to be created (subject to the 14-day rule and prohibition on implantation). Although it was noted that there is currently no research demand for the creation and use of 'true' hybrids (other than for the hamster test), they did not rule out their usefulness in future.⁹⁹

⁹⁷ QQ19, 35, 854–856 and 942, Ev38, para 6, Ev08, para 1.3, Ev09, answer to Q8, Ev28, comment on clause 17, Ev60, para 4.1, Ev67, para 3, Ev71, para 2,

⁹⁸ Q35, Ev38, para 6, Ev08, para 1.3, Ev09, answer to Q8

⁹⁹ QQ35, 93, 786–790 and 942, Ev09, answer to Q8, Ev28, comment on clause 17

160. The Government sought to explain the difference in principle between a hamster-human ‘true’ hybrid, which is destroyed at the two cell stage, and any other sort of ‘true’ hybrid, which would, in any event, be destroyed by the 14-day stage at the latest. Mr Ted Webb, Director of Scientific Development and Bioethics at the Department of Health, described the hamster test as an exemption from the general rule that ‘true’ hybrids would be banned (Q 252) and on another occasion he stated simply that the draft Bill makes the distinction and that the hamster test is used for a very specific purpose. (QQ 559–561)
161. We consider that the Government’s approach on this issue is misguided and rests on no sound point of principle. 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.**

Section 4A(5)(e): the ‘catch-all’ provision and the regulatory gap

162. The Government’s approach to defining inter-species embryos has caused us much difficulty, in particular the ‘catch-all’ provision in subsection (e) and this is reflected in the number of submissions we have received. The Government’s intention is that the ‘catch-all’ will bring within the regulatory regime new types of inter-species embryo which may emerge in the future and it has been explicit that this is only intended to catch entities which are at least 50% human, but which have been created using a process other than fertilisation.¹⁰⁰ This has given rise to two issues. The first is the meaning of subsection (e) itself. We have received an overwhelming body of evidence that its meaning and effect are unacceptably unclear.¹⁰¹ For example, Professor Blakemore said that the Medical Research Council had pored over this provision and “decided that we are all incompetent” because none of them could understand what subsection (e) meant. (Q 25) We see this as a fundamental flaw in the Government’s approach to the definition of inter-species embryos.
163. The second issue centres on the human-animal boundary and which entities should be regulated as human embryos and which should be regulated under the Animals (Scientific Procedures) Act 1986. We have received a lot of evidence suggesting that there is no principle, as such, which underpins the Government’s choice of 50% as a cut-off point for whether an entity is sufficiently human to merit regulation by the HFEA, or whether it is more appropriately regulated as an animal by the Home Office. The 50% rule intended to be embodied in subsection (e) is essentially an arbitrary attempt to draw a line between what qualifies as human and what as animal.
164. We heard evidence arguing that the issue as to what proportion of the entity is human and what proportion is animal is not clear-cut. For example, Professor Martin Bobrow, Chair of the Academy of Medical Sciences working party on interspecies embryos, told us that what makes an entity human rather than animal is not easily measured in DNA terms, although, if a line in the sand had to be drawn, he saw no reason why it should not be

¹⁰⁰ Letter from Department of Health to the Clerk, 12 June 2007, see Appendix 9

¹⁰¹ Ev12(a), comment on clause 17(2), Ev38, para 8, Ev09, answer to Q7a, Ev59, para 8, Ev84, para 3, Ev85(a), para 2, QQ25, 35, 613–614, 647–649 and 773

drawn at 50%. (Q 936) Professor Sir Richard Gardner, Edward Penley Abraham Research Professor of the Royal Society in the University of Oxford, raised the more technical issue of what the 50% actually refers to—for example, when calculating the relative quantities of mitochondrial DNA (which may come from a cow egg) against quantities of nuclear DNA (which may come from a human skin cell), different answers would result according to whether you measured the mass or the number of genes. (Q 791) Dr Robin Lovell-Badge, Head of the Division of Stem Cell Biology and Developmental Genetics at the Medical Research Council National Institute for Medical Research, explained to us that:

“... it is very hard to come up with any strict definition saying this is 50 per cent human and 50 per cent animal, therefore it falls into this category rather than this one, because things change ... You may start off with an embryo which is 20 per cent human and end up with something which is 60 per cent human or vice versa.” (Q 621)

165. This raised the third issue of the interface between the regulatory regime for human embryos and that for animals. The issue arises out of the boundaries between the 1990 Act, as amended by clause 17(2) of the draft Bill, and the Animals (Scientific Procedures) Act 1986. The 1986 Act regulates “protected animals” which are defined in section 1 as any living vertebrate other than man from the time when half the gestation or incubation period for the relevant species has elapsed. However, subsection 4A(3)(c) of the 1990 Act, as amended by the draft Bill, would only allow development of inter-species entities to the earlier of the 14-day stage; the appearance of the primitive streak; or the time when half the gestation or incubation period for any species whose DNA is contained in the embryo has elapsed. The intention behind section 4A(3)(c) is to avoid conflict with the Animals (Scientific Procedures) Act 1986 in cases where half the gestation period for the relevant species is less than 14 days.
166. We note the potential problems this could cause for researchers who may wish to take a mouse-human cytoplasmic hybrid, for example, to the 14 day stage, since the half-way point for the gestation of a mouse is around nine days. (Ev84, para 3) Professor Bobrow explained the effect of subsection 4A(3)(c):
- “If you have a human embryo with some mouse DNA, it cannot be carried beyond in that case nine and a half days, half of the mouse’s gestational age. There is a tighter restriction on that than on a fully human embryo. It is my understanding that the only rationale for blocking this group of experiments between nine and a half and 14 days is the administrative inconvenience of having to coordinate two regulatory regimes which is not to me a very persuasive argument.” (Q 940)
167. We are concerned that section 4A(3)(c) as it stands would have the potential to prevent useful, and possibly established, research from being carried out, as Professor Bobrow explains. This problem contributes to the reasoning behind our recommendation on an alternative approach to defining inter-species embryos in paragraphs 174 to 176.
168. We recognise that the ‘catch-all’ in subsection 4A(5)(e) is at least partly motivated by the practical desire not to include in the regulatory regime for tissue and embryos entities which should more properly be considered as animals and, therefore, subject to regulation by the Home Office under the

1986 Act. Mr Ted Webb told us that the Department was working with the Home Office to ensure that the relevant legislation was consistent. (Q 530) As currently drafted, anything that did not fall into categories (a) to (d) and was less than 50% human would remain outside the remit of the regulator and if the entity was not placed in an animal, it would not fall within the regulatory remit of the Home Office until it reached the time at which half its gestation period has elapsed.

169. We acknowledge that, even outside the regulatory framework, researchers would need to gain approval for any work of this type from the Local Research Ethics Committees. (Ev62, para 8(b)(i)) However, we remain concerned that there is a category of entities which would not be regulated under either the draft Bill or the 1986 Act. We note evidence from the Academy of Medical Sciences that “regulatory questions will increasingly arise from research involving non-human embryos and animals incorporating human material ... we consider that the interface between the regulatory regimes governing human embryos, human embryonic stem cells and animal research will become increasingly important. (Ev84, para 3) It is therefore important that a solution to this problem is found before the Bill is presented to Parliament.

A way forward with definitions

170. There is a large degree of agreement that subsections 4A(5)(a) to (d) are clear definitions. However, we note the significant issues raised in relation to the ‘catch-all’ definition proposed in the draft Bill and we have sought to find an alternative approach.
171. Some witnesses supported discretion for the regulator to interpret definitions in particular circumstances. For example, the HFEA told us they would prefer that the regulator should be left to take decisions about what constitutes an ‘inter-species embryo’ rather than introducing confusion into the Act in the form of an unclear ‘catch-all’ definition. (Ev12(a), on clause 17(2))
172. Many more witnesses, including the BMA, the Royal College of Obstetricians and Gynaecologists and the Wellcome Trust and MRC, favoured an approach where section 4A(a) to (d) remained but the ‘catch-all’ would be replaced by a regulation-making power for the Secretary of State to extend this definition if, in the future, clear proposals for research falling outside the existing definition were presented.¹⁰² This approach would also seem to satisfy Professor Sir Ian Kennedy’s three tests:

“For the purposes of the regulator what there has to be is first of all clarity; secondly, some degree of collective agreement around whatever is clearly being expressed; and, thirdly, some capacity to have a process of negotiation if some challenge to that definition which previously was deemed to be clear appears, warranting some further form of words ...”(Q 775)

173. We consider the Government’s approach to the definitions of inter-species embryos to be wholly unsatisfactory, particularly in respect of the ‘catch-all’ definition in subsection (e)—a definition that none of our witnesses was able to explain to us. We also reject the approach proposed by the BMA and others that the ‘catch-all’ in subsection (e) should be replaced by a regulation-making power for the Secretary of State to extend definitions of

¹⁰² Ev38, para 8, Ev08, para 1.4, Ev09, paras 7a & 7b, Ev09(a), answer to Q2, Ev36, para 1.4

inter-species embryos if, in the future, proposals for research falling outside the existing definition were presented. It is entirely unsatisfactory to have an area of regulation as important as this defined by Ministerial Order.

174. While taking evidence, we sought views on an alternative approach in which section 4A as a whole would be replaced with a single, overarching definition of an inter-species embryo. We sought evidence from several witnesses on this approach and there was little opposition to the concept of a single, broad definition *per se*.¹⁰³ Mr Ted Webb agreed that this approach had the merit of simplicity, but objected that it would encroach on “Home Office territory”. (QQ 532–533)
175. In the time available, we have clearly not been able to provide a final definition, but what we propose below is a starting point to illustrate our thinking. We have sought advice from several witnesses, including Professor Bobrow, on the proposed definition, and their feedback has been very useful.¹⁰⁴ We recognise that further work would be required to amend this draft to deal with certain problems that it entails, for example, the definition would catch some entities that are not appropriate for regulation by the HFEA. There may also be the potential for regulatory overlap with the Home Office. However, we believe these problems are not insurmountable. Above all, it is important to have a definition that is clear and understandable to everyone.
176. With the caveats above, we set out our thinking in Box 1 so the Government is clear about our intention.

BOX 1

Inter-species embryo: working definition

“An inter-species embryo is an embryo which—

- (a) contains genetic material of human and animal origin, and
- (b) in which the genetic material of human origin consists of at least a complete haploid set of human chromosomes in one or more cells.”

In this definition genetic material means DNA in a form capable of being expressed, mutated and replicated heritably (i.e. genes).

Overall conclusion on inter-species embryos

177. As set out above, we have had evidence of strongly held views in favour of and against inter-species embryos. We recognise that this is a very sensitive area. Indeed, this sensitivity was reflected in our own discussions. Some members of the Committee hold strong reservations about the creation of inter-species embryos while others are supportive of this area of research; and we have been unable to reach a consensus on this point. **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.**

¹⁰³ QQ625–639, Q943

¹⁰⁴ We sought advice from Dr Stephen Minger, Professor Roger Brownsword, Helen Munn and Martin Bobrow from the Academy of Medical Sciences Working Group on Inter-species Embryos, the Medical Research Council, Professor Neva Haites, Austin Smith and Lord Patel.

178. **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.**

Prohibitions in respect of embryos and mitochondrial DNA from two women (artificial gametes)

179. Clause 16(2) introduces the new concept of “permitted” eggs, sperm and embryos, which are the only entities which may be placed in a woman. This is the mechanism used in the draft Bill to distinguish those practices in relation to gametes and embryos which are licensable for research purposes and those practices which are licensable for treatment purposes. The definitions of “permitted egg”, “permitted sperm” and “permitted embryo” are given in clause 16(5), new section 3ZA(2) to (4). These definitions prohibit in each case the alteration of nuclear or mitochondrial DNA. The combined effect of these provisions is a prohibition on placing in a woman artificial gametes, genetically modified gametes, genetically modified embryos and embryos created by cloning.
180. Clause 16(5) also introduces a new section 3ZA(5) which confers on the Secretary of State a power to make regulations (subject to affirmative resolution) to extend the definition of “permitted embryos” and “permitted eggs” to include an embryo or egg which “has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease”. As a result of the other provisions in clause 16, subsection (6) repeals the Human Reproductive Cloning Act 2001.
181. Because other provisions in the 1990 Act, as amended by the draft Bill, assume that only one woman’s egg would be used to produce a child, clause 34 is necessary in order to make regulations (by affirmative procedure) to effect certain consequential amendments. Examples of provisions requiring amendment include the registration of donor information (section 31); the ability of donor-conceived individuals to request information about their genetic parentage (clause 32, new section 31ZA); and the provision of information about donor-conceived genetic siblings (clause 32, new section 31ZD).¹⁰⁵
182. The evidence we have received on the combined effect of clauses 16 and 34 has been divided. On the one hand, the Royal College of Pathologists argued that there was no reason why regulations should not ultimately permit the practice of mitochondrial donation, subject to verification of its safety.¹⁰⁶

¹⁰⁵ Explanatory Notes, paras 149–150

¹⁰⁶ Ev06 (2), comments on Part 4

Another witness went further and argued for a range of artificial gametes to be allowed in order that research should not be inhibited. (Ev67, para 2)

183. However, other witnesses objected to the provisions, not least because of a lack of clarity in the explanation about the underlying intention and anticipated effect. Concern principally centred on two issues. First, some witnesses' concern stemmed from their interpretation of the provisions as providing for the possibility that, subject to regulations, an embryo could be created from the genetic material of two women, without the need for fertilisation by a male sperm. They argued that a child having two biological mothers and no biological father was likely to become confused about its identity.¹⁰⁷ One witness considered this technology to be an "abuse" and considered the ethical concerns to be strong enough that further debate would be needed in Parliament when the need arises. (Ev26, paras 17, 19)
184. While we understand these concerns—and we too have found the provisions of the draft Bill extremely difficult to understand—we do not believe that the draft Bill would have this effect. There remains a continuing requirement in subsection (5) (new section 3ZA(4)(a)) for a "permitted embryo" (one which may be placed in a woman) to be fertilised by "permitted sperm". "Permitted sperm" must be "produced by or extracted from the testes of a man" and the Secretary of State has no power to extend the definition of "permitted sperm" to include any alteration of its nuclear or mitochondrial DNA. Our understanding is that, even if scientific development were such that the ability existed to create an embryo from the genetic material of two women, the draft Bill would not allow an embryo so created to be placed in a woman.
185. In our deliberations, we considered the case of a child created using the mitochondrial donation procedure under new section 3ZA(5) and whether it might be said to have three parents: two female and one male. We suspect that the Government's intention in this respect is that the child should have only two registered parents—those whose nuclear DNA was used to create the embryo—but that the child should be able to discover the identity of the female donor of mitochondrial DNA from the Register of information in the same way as other donor-conceived individuals. This is not entirely clear from the draft Bill and Explanatory Notes, although the Department of Health did provide further information on this point in a memorandum to the House of Lords Delegated Powers and Regulatory Reform Committee. This memorandum suggests that the power in clause 34 might, for example, be used to clarify that the woman who donated the egg with healthy mitochondria could not apply for a parental order on the basis that she only contributed mitochondrial, not nuclear, DNA to the embryo.¹⁰⁸
186. **We therefore 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**

¹⁰⁷ Ev13, heading on Treatment Conditions, Ev62, para 7(a)(ii)

¹⁰⁸ Department of Health memorandum to the House of Lords Delegated Powers and Regulatory Reform Committee, May 2007, para 57

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.

187. The second concern raised by witnesses was that substituting the Human Reproductive Cloning Act 2001 with clause 16 would create a loophole that would legalise human reproductive cloning.¹⁰⁹ Again, we do not consider this to be the case because the definitions of “permitted” egg, sperm and embryo, which are the only entities allowed to be placed in a woman, preclude this possibility. Simply put, a cloned embryo would not qualify as a “permitted embryo” for the purposes of clause 16 and, therefore, could not legally be placed in a woman.
188. **We therefore 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.**
189. Returning to the actual effect of the provisions, given that any regulations under clauses 16 and 34 must be passed subject to the affirmative procedure, we are satisfied that this will provide sufficient opportunity for parliamentary scrutiny should genetic modification to prevent serious mitochondrial disease be considered safe in the future.

Clause 18 and Schedule 2: Licensable activities

190. Clause 18 provides that the activities which may be licensed under the 1990 Act, as amended, are listed in Schedule 2. The Schedule starts with some amendments to the existing provisions for treatment licences (paragraph 2). Paragraph 3 inserts new provisions for embryo testing and sex-selection, including a power to amend these provisions by regulations. Some amendments are made in paragraph 4 to existing provisions on licences for non-medical fertility services introduced as a result of the EU Directive on tissue and cells. Paragraph 5 inserts a new provision allowing for regulations to be passed to permit storage of inter-species embryos, although this draft provision will likely be amended in the light of the Government’s change of policy on inter-species embryos. Finally, new provisions on research licences are set out in paragraph 6.
191. We have not had sufficient time in this inquiry to consider in detail all of these provisions. Nevertheless, we have concentrated on a few, important issues, namely embryo testing under paragraph 3 and research licences under paragraph 6. Our findings on these issues are set out below.

Embryo testing

192. The HFEA currently has a wide discretion to make licensing decisions in relation to embryo testing of various sorts. The draft Bill introduces specific provisions which set out the framework for licensing embryo testing, including the selection of ‘saviour siblings’ and the cases in which sex-selection may be permitted.
193. Paragraph 3 of Schedule 2 of the draft Bill inserts new paragraph 1ZA which makes provision in relation to embryo testing. Under paragraph 1ZA(1), a

¹⁰⁹ Evening Forum Report, Appendix 5, Ev92, Ev97, Ev52, para 19, Ev56, Ev61 and Ev66

licence may not authorise embryo testing except for one or more of five listed purposes. These purposes include testing for gene, chromosome (including X or Y chromosome) or mitochondrion abnormality which may affect capacity to result in a live birth or result in a serious medical condition; testing to select a ‘saviour sibling’ where the existing sibling suffers from a life-threatening medical condition which could be treated by umbilical cord blood stem cells; and testing whether a given embryo was created from the gametes of a particular person. New paragraph 1ZA(3) sets out the tests for considering whether the issue of a treatment licence is necessary or desirable under paragraph 1(3) of Schedule 2 of the 1990 Act. New paragraph 1ZA(4) sets out further considerations for which the regulator must have regard when taking a decision to issue a licence to test for a ‘saviour sibling’.

194. We have received evidence on the subject of embryo testing generally, and in particular regarding the use of the technique of pre-implantation genetic diagnosis (PGD). Opinions on both sides of this debate are strong and we recognise the profound objection expressed by some witnesses to the idea of any type of embryo testing. However, whilst embryo testing techniques, although perhaps not widespread, are reasonably well established, we will not discuss further in this report whether or not the Government should retreat from the status quo and move to proscribe such practices.
195. We recognise that embryo testing is an issue of considerable sensitivity for some. However, on balance, we support the provisions set out in the draft Bill. We will, however, consider in more detail the evidence we have received in relation to ‘saviour siblings’ and sex selection.

Tissue typing and ‘saviour siblings’

196. Where an existing child suffers from a life-threatening medical condition which could be treated by umbilical cord blood stem cells, new paragraph 1ZA(1)(d) permits as a licensable activity testing to select a sibling with a suitable tissue type to enable treatment of the existing child. For this reason, the child selected is often known as a ‘saviour sibling’. The additional safeguards in section 1ZA(4) require the regulator, before granting the licence, to have regard to any alternative sources of tissue which may be or become available for treating the child; and the likely long-term effect of awareness of the testing on any child who results from the embryo testing. We are not convinced that the likely long-term effects on the resulting child are easily ascertained, as the draft Bill requires.
197. As with other types of embryo testing, the evidence on this issue, although not particularly plentiful, has been split. Some people regard the selection of saviour siblings in the same light as all embryo testing and are fundamentally opposed to the practice. (Ev72, para 3) It has been argued that the practice of tissue typing raises serious ethical problems, because a child is viewed not as a gift, but as a source of biological material. (Ev97)
198. Others have argued that the new provisions are actually too restrictive. The HFEA has expressed concern that the requirement that the existing child suffers from a life-threatening condition capable of treatment by umbilical cord blood stem cells is more restrictive than the current regime and would prevent the selection of a sibling who would be able to provide bone marrow, for example. The HFEA considers that this requirement would be difficult to enforce and would restrict its capacity to respond appropriately to individual cases. (Ev12(a) Appendix A) Professor Sally Sheldon, from the Kent Law

School at the University of Kent, and Professor Stephen Wilkinson, from the Centre for Professional Ethics at Keele University School of Law, have agreed with the HFEA's view. They did not understand the restriction to "life-threatening medical conditions" and suggested that the provision should be expanded to include "serious" medical conditions. They and others noted further that the requirement that the condition be capable of treatment by umbilical cord blood stem cells would not necessarily prevent the resulting child from being used as a tissue or organ donor at a later stage in life.¹¹⁰ However, we also note that the issue of donation subsequent to birth is not within the remit of the HFEA and is covered by common law. Although the regulator must take into account the likely long-term effect of awareness of testing for tissue type on the resulting child, it has been suggested that the safeguards for that child's welfare should be strengthened further.¹¹¹

199. **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".**

Sex selection

200. The HFEA currently permits sex selection of embryos only for medical reasons. Schedule 2, paragraph 3, of the draft Bill would permit under licence sex selection of embryos, by embryo testing or other practices, but only to avoid a significant risk that the resulting child will have or develop a serious medical condition. New paragraph 1ZC introduces a power for the Secretary of State to make regulations to amend the provisions on embryo testing, but the provisions on sex selection may only be amended on grounds relating to the health of the child.
201. In evidence, we explored the possibility of widening the scope for sex selection for non-medical reasons beyond that permitted by the draft Bill, in particular for family balancing. Some witnesses were entirely opposed to sex selection, even for medical reasons, on ethical grounds.¹¹² At the other extreme, witnesses have argued that there is no evidence that demonstrable harm would result from a policy allowing sex selection for non-medical reasons, for example, family balancing. Professor Brownsword thought that it was essentially a matter of human rights and reproductive autonomy. (Q 45) The British Fertility Society told us "We have seen no convincing evidence of harm from sex selection in the UK, and do not believe that there is likely to be enormous uptake of this kind of service." (Ev23, para G) The organisation Antenatal Results and Choices argued that "fears about women or couples en masse seeking [Pre-implantation Genetic Diagnosis¹¹³] to try to secure a 'designer baby' are unwarranted" and favoured allowing sex selection for non-medical reasons, subject to regulation, to benefit a relatively small number of parents, who could make an informed choice together with clinicians.

¹¹⁰ Ev89, Ev21, para 3

¹¹¹ Ev21, para 1.2, Ev68, para 10

¹¹² For example, Ev35, answer to Q10, Ev55, answer to Q10

¹¹³ A method by which sex selection may be carried out

202. The majority of witnesses, including the BMA and the Royal College of Obstetricians and Gynaecologists, were in favour of sex selection as long as it was only for medical reasons.¹¹⁴ Some thought that to go further than this would amount to the UK setting a bad example on the international stage.¹¹⁵ For example, the Royal College of Obstetricians and Gynaecologists, who have members and fellows throughout the world, told us “If we came out in support of sex selection this would send a very clear message saying, ‘Whatever means you wish to select for boys or girls is okay’, so that is a very difficult message to send out.” (Q 126) It was also argued that it would place a value on gender which some considered undesirable. (Q 43; Ev8, para 4)
203. The HFEA told us that their public consultation carried out in 1993 showed that participants were overwhelmingly against sex selection for social reasons. A further review exercise, starting in 2002, considered sex selection from social, ethical, scientific, technical, legal and regulatory perspectives. (Ev12(a), Appendix B, paras 1 and 3) They told us that the results of the 2002 review once again demonstrated that, in general, participants were tolerant of sex selection for medical reasons, but were generally opposed if it were to be used for social reasons. In coming to a policy decision based on the review, the HFEA noted that widespread public hostility to a policy allowing sex selection for non-medical reasons would not necessarily show that that policy was wrong. However, the HFEA concluded that the likely benefits of permitting sex selection for non-medical reasons were not substantial enough to merit a policy going against public opinion in this case. The HFEA therefore recommended that sex selection for non-medical reasons should not be permitted. (Ev12(a), Appendix B, para 32)
204. The HFEA contrasted its current policy, that sex selection is not permitted for non-medical reasons, with the approach in the draft Bill, under which sex selection is only permitted for reasons connected with the health of the child. The HFEA argued that the wording of the draft Bill effects a more restrictive approach than the HFEA’s current policy, and that this may lead to future problems. It gave as an example conditions which correlate with sex but are not X-linked, such as autism—the draft Bill would bind the regulator’s hands if tests for non X-linked conditions became possible in the future. (Ev12(a) Appendix A)
205. We recognise that there are finely balanced arguments on either side. **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.**

Research licences

206. Paragraph 6 of Schedule 2 extends the list of purposes for which a research licence may be granted. These provisions make significant changes to the current arrangements. First, new paragraphs 3A(1)(a) and (b), inserted by the draft Bill into Schedule 2 of the 1990 Act, extend the existing arrangements to cover “serious medical conditions” as well as “serious disease” so that, for example, research into neural trauma, which is not a

¹¹⁴ Ev05(a), Ev38, para 11, Ev12(a), para 32, Ev26, answer to Q17, Ev29, para 2.1, Ev38, para 4.1, Ev43, para 7, Ev51, para 10, Ev56, para 5, Ev58, para 16, Q42

¹¹⁵ Ev51, para 10, Q126, Q128

disease as such, would be permitted. Second, new paragraph 3A(1)(b) allows for the licensing of research “which may be capable of being applied” to increase knowledge or develop treatments for serious medical conditions. This is intended to allow fundamental research which, while not specific to any disease or condition, nevertheless could lead to better understanding of fundamental phenomena on which more specific future research into serious disease or conditions may be based.¹¹⁶

207. We received limited evidence about this extension of licensable research purposes. The HFEA welcomed the widening of the research purposes, and told us the current system had worked well by providing a strong framework for case-by-case decision making, thus enhancing public confidence. (Ev12(a), paras 27–28) The MRC welcomed the strong guidance and saw this as a valuable mechanism for Parliament to make clear its intentions. (Ev9, para 8) Others have welcomed the clarification that fundamental, as well as applied, research is licensable.¹¹⁷ We consider the clarity of the conditions on research licenses might be focussed by expanding on the two tests that the MRC uses for assessing applications for financial assistance, namely how important the questions, or gaps in knowledge, are that are being addressed, and what the prospects are for good scientific progress.
208. In the light of this evidence, we consider the extensions to the existing research purposes to be sensible and we therefore support these provisions.
209. Another issue arose from the provisions on research licences. Paragraph 3(4) of the 1990 Act currently prohibits the altering of the genetic structure of a cell of an embryo unless this is specifically permitted in regulations. No such regulations have ever been made. The draft Bill omits this prohibition from the section on research licences, so that genetic modification of embryos may now be permitted for research purposes under licence.¹¹⁸
210. Some witnesses saw this as a move to open the door to genetic engineering. For example, we were told that the “Government may not have fully appreciated the far-reaching consequences of such a decision” and that it raised concerns about eugenics. (Ev56, section 2) The Church of England Mission and Public Affairs Council saw this as “a dangerous and unwarranted change”. They noted that scientists were not calling for such research to be permitted and said they are “at a loss to know why the Government would countenance such an action”. (Ev68, para 19(i))
211. In its White Paper, the Government made clear its continuing opposition to genetic modification for treatment purposes, but stated that the need to proscribe genetic modification for research purposes was less clear.¹¹⁹ Such research would, in any event, be required to meet the statutory research purposes and any additional licence conditions which may be imposed by the regulator.
212. 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**

¹¹⁶ Explanatory Notes, paras 73–78

¹¹⁷ Ev48, para 11, Ev84, para 4

¹¹⁸ Explanatory Notes, para 79

¹¹⁹ White Paper, paras 2.48–2.52

clarifies its policy decision to allay the concerns which have been expressed.

Consent to storage and use of gametes and embryos

213. Schedule 3 to the draft Bill adds a requirement to the 1990 Act that written consent must be signed by the consenting person in relation to the storage or use of gametes and embryos. Provision is made for those unable to give consent in writing through physical incapacity, such as quadriplegia, to direct another to sign on their behalf in the presence of a witness. Paragraph 5 introduces a “cooling off period” in cases where consent to storage and use of gametes and embryos is being withdrawn. Paragraph 8 of Schedule 3 also provides for storage of gametes in cases where a person is unable to give written consent or unable to consent at all, either through incapacity or, in the case of a child, a lack of competence. We have had evidence in relation to two aspects of these provisions
214. We have received evidence, first, about the ‘cooling off’ period which applies when consent has been withdrawn; and, second, in relation to cases in which storage of gametes can occur without consent. The draft Bill provides that notice of withdrawal of consent to storage and/or use of gametes or embryos must also be made in writing and signed by the person withdrawing consent. Notice served on the establishment storing or keeping gametes will result in those gametes being allowed to perish. In the case of embryos, paragraph 5 is intended to provide a 12 month “cooling off period” during which the parties can attempt to resolve any differences between them, either privately or through the courts.
215. The BMA welcomed this provision. (Ev07, para 13) The HFEA also supported a cooling off period, but were concerned that the provision as currently drafted would not distinguish between, on the one hand, cases where the embryo is created with the gametes of two partners and, on the other hand, cases where the embryo is created with one or more donor gametes. For example, where an embryo has been created using a woman’s (W) egg and donor sperm, the current provision would suggest that, if W gave notice to the clinic that she no longer consented to the storage of that embryo, the clinic would be required to notify the donor and keep the embryo for a year, unless the donor gave his consent to its destruction before that time. The HFEA did not think that this was the intention behind the clause.¹²⁰ **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 in Schedule 3 to the draft Bill.**
216. The second issue raised in evidence related to storage without consent. Some witnesses welcomed these provisions.¹²¹ However, the British Fertility Society expressed concern that these provisions may expose clinicians to allegations of assault. (Ev23, para H) The British Infertility Counselling Association was uncomfortable with the removal and storage of gametes without consent, but accepted that it may be necessary in cases of severe illness or for legal minors. In such cases, they argued that proxy consent should be obtained. (Ev43, para 8)

¹²⁰ Ev12(a) Appendix A, comment on Schedule 3 para 5

¹²¹ Ev34, para 8, Ev29, para 2.10.

217. On a more detailed point, the Royal College of Pathologists argued that one of the conditions in paragraph 9 stipulates that the “gametes are lawfully taken from or provided by” the child donor or patient. Their concern was that gametes could only be lawfully obtained by consent and, if consent was given for that purpose, it is highly unlikely that consent to storage would not be given at the same time, since storage would generally be the purpose of taking the gametes in the first place. They told us that “To provide for gametes to be stored without consent is likely to give rise to the situation where lack of clarity leads to storage where gametes have not been legally obtained”. (Ev06, Part 2, para 10)
218. 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.**

Conditions of licence for treatment: ‘Welfare of the child’ and ‘need for a father’ provisions

Introduction

219. Clause 21 of the draft Bill proposes changes to section 13 of the 1990 Act covering the conditions of licences for IVF treatment, including:
- (i) Removing the words “(including the need of that child for a father)” from section 13(5) of the 1990 Act. The effect of this change would be to remove from the existing conditions of treatment licences the requirement for clinics to take account of the need for a father of any child which may result from fertility treatment before providing treatment services. The duty on treatment licence holders to consider the welfare of the child who may be born as a result of treatment, or the welfare of any other child who may be affected by the birth, remains.
 - (ii) Applying the requirement to take account of the welfare of the child to all basic treatment services covered by the 1990 Act, including those brought within the HFEA’s remit by the transposition of the EU Tissue Directive into UK law.
 - (iii) Extending the existing requirements to provide counselling.
220. We received relatively little evidence on proposed changes (ii) and (iii) above, and what we did receive was largely supportive of the provisions in the draft Bill. Lady Julia Tugendhat, Vice President of the British Association for Counselling and Psychotherapy, told us that counselling was “very important throughout, through every stage, and sometimes not enough emphasis is given to the early stages, where people are trying to make decisions”. (Q 415) The South East Post Adoption Network argued that legislation should make it mandatory “for prospective parents to attend counselling, preparation and information sessions prior to receiving donated gametes”. (Ev54, para 3.5) We do not support mandatory counselling. By contrast, we received a large

amount of evidence on the duty to consider the ‘welfare of the child’ generally, which will remain in the 1990 Act as amended by the draft Bill, and on the proposal to remove the ‘need for a father’ provision. We discuss these issues in more detail below.

Welfare of the child

221. In this area, as in others covered by the draft Bill, there has been a debate about whether the welfare of the child should be paramount. The Minister told us that “Welfare of this child is paramount here”. (Q 580) This stance was supported by many who gave us evidence. For example, Professor Andrew Fergusson, Head of Communications at the Christian Medical Fellowship, felt that the right of the child should be paramount because of the child’s vulnerability. (Evening Forum Report, Appendix 5)¹²² The Rt Revd Dr Lee Rayfield, Bishop of Swindon, noted that the Adoption and Children Act 2002 stated that the welfare of the child should be paramount (Evening Forum Report, Appendix 5). However, Professor Raanan Gillon, Emeritus Professor of Medical Ethics at Imperial College London, told us that “It seems to me that one needs to be very careful about the welfare of the child being paramount, it does not seem to me that this is the normal reason for having a child”. (Q 865) Whilst we understand and share the view that the welfare of the child is extremely important, the word ‘paramount’ indicates ‘above all else’ and this may present legal difficulties. We therefore support retaining the current position of ‘taking into account’ the welfare of the child.
222. Others told us that the ‘welfare of the child’ provision should be removed from the statute book. Professor Peter Braude, Head of the Department for Women’s Health at King’s College London, and Chairman of the Scientific Advisory Committee (SCAG) of the Royal College of Obstetricians and Gynaecologists, argued that neither provision should be in statute but should be left to the judgement of the doctor providing that treatment in accordance with good medical practice: “It is the one [provision] that caused the most havoc” in terms of getting the right paperwork to the HFEA. (QQ 132–133) Dr Gillian Lockwood, Medical Director of Midland Fertility Services, argued that there should be more equality of treatment with those conceiving naturally: “I do not think we should put IVF treatment in some little hallowed glass box and make everyone better than the rest of society”. (Q 471) The British Medical Association acknowledged that there was a clear difference from those who conceived naturally because of the involvement of a third party with assisted reproduction. (Ev07, para 15) CARE similarly argued that when prospective parents go to a fertility clinic for assistance in creating a child, “it becomes a public not a private issue”. (Ev66, para 1.5)
223. Professor Margaret Brazier of the Centre for Social Ethics and Policy, School of Law, University of Manchester, argued that the clinic providing treatment and the professionals who deliver that treatment “share in the responsibility for the birth of the child”. (Ev109, para 8) We consider that the special status of the embryo distinguishes this case of third party involvement from others where the creation of an embryo is not part of a procedure.

¹²² See also Ev52, para 13, Ev53, Ev78, Ev97, para 12, Ev103, Ev26, para 13, Ev50, para 2.0

*The 'need for a father'**Reasons for proposed change*

224. In its White Paper in December 2006, the Government said it was “not convinced that the retention of this provision could be justified in terms of evidence of harm, particularly when weighed against the potential harms arising from the consequences of encouraging some women who wish to conceive to make private arrangements for insemination rather than use licensed treatment services”.¹²³ Since then, the Government has given us a number of further reasons why they propose to remove this provision.
225. Mr Ted Webb told us that the current legislation “does not actually seem to achieve anything. So we have looked at it from a legalistic point of view more than anything else. It does not prevent treatment being provided to single women or same-sex couples, and also does not seem to fit too comfortably with the Government’s wider civil partnerships policy. So I think that is really our starting point for recommending that the need for a father reference is taken out of the legislation”. (Q 256) When asked whether this was a decision made on a legalistic argument rather than any other area of consideration, he replied “That is right” (Q 257), but later clarified that this was “in the context of the assessment of the welfare of the child”. (Q 260)
226. In oral evidence, the Minister told us that the current 1990 Act provision “does not prevent someone having access to fertility treatment as a single woman, whether she is heterosexual or gay” and in this context, having to take into account the need for a father presented all sorts of issues and was “illogical”. (Q 578) Furthermore, she commented that the current provision was “very difficult to implement in any rational way” and that “To be honest, we have a piece of legislation which says one thing in terms of legal entitlement and then has a caveat which is difficult to enforce in any coherent way. I am not sure if that is good law.” (QQ 582, 585)
227. The evidence we received on the proposal to remove the ‘need for a father’ provision was highly divided. The HFEA took the view that “considerations relating to the welfare of the child should not make reference to particular family structures”. (Ev12(a), para 34) Hugh Whittall thought that there were many families who do not have a father present and that it was “timely to recognise this by concentrating on the welfare of the child”. (Q 53) Dr Vivienne Nathanson, Director of Professional Activities at the British Medical Association (BMA) said “we think that the evidence is that what children need is security, unconditional love, all of those things, and that does not necessarily mean a father”. (Q 131) Dr Tony Calland, Chairman of the Medical Ethics Committee at the BMA, added that “the words about need for a father are perhaps slightly emotive” and that the welfare of the child can be provided for by a loving relationship with two parents who “may be two male parents who have had a child by a surrogacy”. (Q 134)
228. Professor Simon Fishel, Managing Director of the CARE Fertility Group was “not sure [the provision] should exist” and acknowledged that while the assessment process was adhered to in order to satisfy the 1990 Act, the need for a father provision did not prevent single women from accessing treatment at his clinic: “Generally, they tend to find a father figure—uncle, brother,

¹²³ Paragraph 2.26 of the Review of the Human Fertilisation and Embryology Act: proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos), Cm 6989

somebody”. (QQ 473, 474) Dr Gillian Lockwood told us “I do not believe it does stop anybody getting treatment and I do not think it should ... We may prefer the ‘Janet and John’ world in which there is a mother and father, a boy and a girl and a dog named Spot but the real world is one of single parents, women deciding to have a baby on their own, or being left pregnant or whatever”. (Q 471) Many other witnesses supported the removal of the ‘need for a father’ provision¹²⁴.

229. On the other hand, there were as many witnesses who told us they opposed the removal of the provision. The Rt Revd Dr Lee Rayfield, Bishop of Swindon, accepted that the Government was motivated by a desire not to discriminate in proposing to remove the provision but said that this was misguided, created confusion and came across as an attempt at social engineering (Evening Forum Report, Appendix 5). Several witnesses argued that the proposal was inconsistent with other Government policies towards fathers. For example, Professor Andrew Fergusson from the Christian Medical Fellowship said that the proposal flew in the face of recent proposals regarding the Child Support Agency. (Evening Forum Report, Appendix 5)¹²⁵ We also note the inconsistency with the removal of sperm donor anonymity to allow donor-conceived persons to trace and identify their donor fathers.
230. Dr Daniel Boucher, Director of Parliamentary Affairs at CARE, argued that rather than removing the provision, it should be made to work better (Evening Forum Report, Appendix 5), an approach supported by others.¹²⁶ The Lawyers’ Christian Fellowship supported retaining the provision on the grounds that “legislation should continue to make clear that fathers are important to children to ensure that this aspect of their welfare is not overlooked” and they stated that other areas of law recognise the importance of two parents in the life of a child. (Ev52, para 12) The Centre for Social Justice argued that the provision operated on two levels: providing a statement of principle in law and in some cases providing useful guidance for clinicians and patients. (Ev53) The Church and Society Council of the Church of Scotland said that to deny the need of a child for a father “would be repugnant, as well as contrary to plain common sense”. (Ev97, para 12) Again, many others opposed the removal of the provision, including several donor-conceived people.¹²⁷

Research evidence on role of fathers

231. We heard from several witnesses involved in research on the influence of the role of fathers on children. Professor Ann Buchanan, Director of the Oxford Centre for Research into Parenting and Children, told us that that from her research, “the evidence for the role of fathers is important” and “is strongly related to children’s later educational attainment. Children with involved fathers are less likely to be in trouble with the police. Father involvement is associated with good parent-child relationships in adolescence. Father

¹²⁴ Q690, Ev58, para 18, Ev54, para 2.3, Ev29, para 2.3, Ev22, para 9, Ev23, para I, Ev25, para 12, Ev30, para 2.4, Ev33, para 3, Ev38, para 6.1, Ev43, para 9

¹²⁵ See also Dr Daniel Boucher of CARE (Evening Forum Report, Appendix 5)

¹²⁶ Ev53

¹²⁷ Ev55, para 12, Ev65, Ev68, para 12, Ev74, para 7, Ev75 and 76, Ev77, para 12, Ev78, Ev13, Ev15, Ev24, para 12, Ev27, para 12, Ev35, para 12, Ev72, para 14, Ev63, Ev44, para 12

- involvement protects against adult experiences of welfare and later mental health problems and it applies in different ways to both girls and boys”. (Q 878) Several other witnesses supported this view, for example, Professor Andrew Fergusson, who stated that everything in social policy research showed that children with fathers do better. (Evening Forum Report, Appendix 5)¹²⁸
232. However, Professor Buchanan also acknowledged from a wider perspective that “if there was one intervention which would increase the wellbeing of children, it should be that children should be wanted and planned for” and “in civil partnerships it may be possible to compensate for the need to have some male presence in the children’s lives”. (Q 880)
233. Professor Susan Golombok, Professor of Family Research and Director of the Centre for Family Research in the Faculty of Social & Political Sciences at the University of Cambridge, told us that “there is really no evidence that having a father is necessary for girls to develop typically or boys to develop typically in terms of gender identity and sexual behaviour”. (Q 883) She highlighted studies which showed that children growing up in single-parent families do less well at school and are more likely to show problems in terms of psychological adjustment than children in two-parent families. However, she went on to say that “these greater difficulties ... are very much associated with the circumstances of being in a one parent family rather than just whether or not there is a father present. For example, a drop in income, to do with lack of social support for the family, a disrupted relationship with the father ... and moving into step families ... It is not simply a matter of there being no father *per se*”. (Q 883)
234. Professor Golombok’s studies of families with same-sex parents, particularly families headed by two lesbian women, “tend to show that children ... are no less disadvantaged in terms of their emotional wellbeing or other aspects of development than children in comparable heterosexual families, which leads to the conclusion that, it is really the second parent that is most important ... more important than the gender of that parent”. (Q 884) She later clarified that “It is the relationship rather than the gender” that was important. (Q 893) This was supported by Professor Buchanan who also said “I think what is absolutely critical here is that there are two parents”. (QQ 890, 894) Similarly, the British Fertility Society in written evidence argued that research showed that children do better when there is “a supportive social network”. (Ev23, para I) Professor Sir Ian Kennedy said that “raising a child by two parents rather than one should be encouraged in all circumstances. Whether the parents are of the same or different sex is less important than there should be two of them”. (Ev108) Professor Søren Holm told us that “to single out the father as the thing that we need to take account of in the welfare calculation, it is very difficult to justify. Why not single out stable income or the presence of a caring mother or something else”. (Q 866)
235. However, Professor Almond, Emeritus Professor of Moral and Social Philosophy at the University of Hull, argued that despite the research evidence “the idea that a mother and a father are both a good thing on the whole for children and also some basic assumption about the structure of family life is undeniable”. (Q 891) In written evidence she urged caution

¹²⁸ See also Ev61, paras 10 and 11, Ev66, para 1.4, Ev68, para 12. CARE provided us with a bibliography of research supporting this view.

“when tampering with something as fundamental as having a parent of each sex”. (Ev21, para 2) Professor John Haldane, Professor of Philosophy and Director of the Centre for Ethics, Philosophy and Public Affairs at the University of St. Andrews, felt that “To engineer a situation in which one of those [mother or father] is to be absent is to wrong a child”. (Q 867) The Centre for Social Justice argued that a wealth of social research findings challenge the notion that deliberately planning to have fatherless children can be in the long term best interests of those children. (Ev53) Despite her research findings, Professor Golombok said that in her view “fathers have been under-valued in many ways and I think, especially over the last 30 years, there has been a change in fathers’ relationships with their children”. (Q 895)

HFEA guidance on the welfare of the child and the need for a father

236. The Minister told us the Government did not want to micromanage from the centre, and acknowledged that it was for the HFEA to issue guidance and for clinicians to make a judgement. (Q 580) Under the 1990 Act, the HFEA is required to provide guidance on the duty to take account of the welfare of any child. The current HFEA Code of Practice, arrived at through experience and a consultation on the welfare of the child provisions with professionals, patients and the public, says a treatment centre should “carry out an assessment of risk of harm to the welfare of the child before providing any licensed treatment”.¹²⁹ (para G.3.1.1) The guidance then sets out the factors the treatment centre should consider, factors “likely to cause serious physical, psychological or medical harm, either to the child to be born or to any existing child of the family”. (para G.3.3.2)
237. In respect of the need for a father provisions, the guidance says that “Where the child will have no legal father, the centre should assess ... the prospective mother’s ability to meet the child’s/children’s needs and the ability of other persons within the family or social circle willing to share responsibility for those needs.” (para G.3.3.3) In addition, the current guidance says that “In particular, patients should not be unfairly discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.” (para G.3.2.2)
238. Once the assessment has been undertaken, the guidance states that “treatment should be refused if the centre concludes that either the child to be born or any existing child of the family is likely to experience serious physical, psychological or medical harm or where the treatment centre is unable to obtain sufficient further information to conclude that there is no significant risk.” (para G.3.4.5)

Alternative proposals

239. Several witnesses proposed that the ‘welfare of the child’ provision should be revised in line with the HFEA guidance. Indeed, the HFEA supported the “vague” wording on the welfare of the child being replaced with wording reflecting their current guidance, cast in terms of the duty to consider whether a child born might be at risk. (Ev12(a), para 36) Professor Brazier felt strongly that “some form of principle should be retained” in legislation but supported an obligation drawn up on the same lines as the Children Act

¹²⁹ Code of Practice: Human Fertilisation and Embryology Authority, 7th Edition, 2007

1989 to “ensure that any child or children born as a result of treatment ‘is not at risk of significant harm’”. (Ev109, para 8) The BMA supported a re-writing of the provision to specifically refer to cases where there is ‘foreseeable risk of serious harm’. (Ev07, para 15) The British Association of Social Workers Project Group on Assisted Reproduction (PROGAR) and UK DonorLink both supported a new provision of likelihood to experience ‘significant harm’. (Ev29, para 3.1)(Ev30, para 4.5) The South East Post Adoption Network (SEPAN) agreed that the requirement to ensure the child would not experience significant harm should be put in primary legislation. (Ev54, para 3.3)

240. However, the Lawyers’ Christian Fellowship expressed concern that HFEA guidance since 1990 had eroded the force of the welfare of the child provisions. In particular, they opposed what they view as a shift in the burden of proof to a presumption of treatment unless there is evidence of serious harm, which they considered to be too high a threshold. (Ev52, para 13)
241. The welfare of a child is a key area where consistent, understandable and enforceable legislation is needed. We support the approach taken in the 1990 Act towards the welfare of the child and the positive shift in HFEA guidance towards a risk-based approach with the presumption of treatment unless information suggests serious harm will be caused.
242. The proposal to remove the ‘need for a father’ provision involves complex ethical and social issues. We have had a weight of evidence on both sides which has been logical and well argued. We note the Government’s intention to ensure that the treatment conditions are not discriminatory and are in line with other legislation such as civil partnerships but have had reassurance from the Minister that the existing provisions do not prevent access to treatment services either to same sex couples or single women. We also note other areas of government policy that take a different approach towards the role of fathers in bringing up children and we have had little evidence that the existing provisions have caused harm. We have found persuasive the evidence presented to us that a loving, supportive family network is more important for a child’s development than the gender of the second parent and we note the provisions on parenthood in the draft Bill, in particular clause 59 in which a reference to a ‘father’ would no longer simply refer to a child’s male parent, but would also refer to a woman who is a child’s parent by virtue of clauses 48 and 49. In an area such as this, the law has symbolic value. Ultimately, however, the issue is one of what is in the best interests of the child.
243. **We recommend that the proposal to remove the ‘need for a father’ provision from section 13(5) of the 1990 Act should be put to a free vote of both Houses of Parliament. To inform that vote, the balance of view of this Committee is that it would be detrimental to remove entirely the requirement to take into account the ‘need for a father’. Instead, we recommend that the current provision in section 13(5) on “(including the need of that child for a father)” should be retained but in an amended form in a way that makes clear it is capable of being interpreted as the ‘need for a second parent’ in line with the parenthood provisions currently in Part 3 of the draft Bill. In making this recommendation, we do not seek to discriminate against single women seeking treatment and we recommend that in such**

circumstances and the requirement to consider the need of a child for a second parent should, as now, not be a barrier to treatment.

Storage limits

244. Clause 22 of the draft Bill would amend section 14 of the 1990 Act so that the statutory storage period for gametes and embryos would be raised to ten years, consistent with the existing storage period for gametes. If the gametes or embryos are still in storage at the end of that period, they shall be allowed to perish. As is currently the case, couples would have the opportunity at any point during the ten year period to donate gametes or embryos for the treatment of others or for research.¹³⁰
245. Some witnesses have called for flexible storage periods for gametes or embryos created or donated destined for treatment to benefit individuals and couples in exceptional circumstances.¹³¹ Sheila Pike from Sheffield Teaching Hospitals NHS Trust, and Kate Grieve from University Hospitals Coventry and Warwickshire NHS Trust, gave the example of embryos created for a surrogacy arrangement prior to a young patient undergoing a hysterectomy or cancer therapy. In such cases, the individual concerned might wish to use the embryos over a period of time greater than ten years and in more than one surrogacy arrangement to create a family. (Ev34, para 10)
246. There were also calls for the current limits on storage for research purposes to be extended or removed entirely. (Ev51, para 14) The British Fertility Society have advocated greater flexibility to deal with the situation where embryos created for treatment purposes, which are suitable for donation for research, become available only a short time before the statutory time limit for storage is reached. (Ev23, para J) Others also felt strongly that embryos created for treatment should be permitted to be used in research after the ten year time limit.¹³² The MRC and the Wellcome Trust said “We believe a longer storage period for research purposes should be permitted so that if a patient wishes and gives consent, the potential value of this precious and valuable resource can be maximised for future research. We ... would advocate a storage period of at least 50 years (as this would be within the normal lifespan of the average donor).” (Ev09, answer to Q14)
247. Similarly, the Royal College of Pathologists argued that banks of material built up for research use should be available indefinitely, with donor consent, since this reflected good practice in research methods and would become a valuable resource. This applied not only to embryos, but also to sperm and oocytes initially banked for research purposes, including as yet undefined future research. Under the current legislation, these would have to be disposed of after 10 years which they considered nonsensical and not an efficient use of “precious funds and resources”. The ethics of disposing of material which patients have donated to research without maximising its potential in this regard were, they thought, questionable. (Ev06, Part 2, para 13) Alison Murdoch, Professor of Reproductive Medicine at Newcastle Fertility Centre, told us that thousands of human embryos are discarded annually because they are no longer needed or wanted for fertility treatment.

¹³⁰ Explanatory notes, para 114

¹³¹ Ev9, answer to Q14, Ev51, para 14, Ev77, answer to Q14, Ev43, para 10

¹³² Ev6, para 13, Ev38, para 7, Ev51, para 14

Her experience was that over 70% of couples were happy for these embryos to be used for research. (Ev17, para 3.3)

248. The HFEA, however, supported the provisions in the draft Bill and agreed that there should continue to be a statutory storage period for gametes and embryos and that a limit of 10 years was reasonable.¹³³ They argued that without a statutory maximum, the storage periods for gametes and embryos would likely be variable, leading to the undesirable outcomes of variable treatment for different individuals and couples as well as the risk that clinics may be required to store gametes and embryos indefinitely in the absence of agreement to their destruction. (Ev12(a), para 24) The Royal College of Pathologists were also content with the statutory time limit in relation to gametes and embryos destined for treatment. (Ev06, Part 2, para 13)
249. We acknowledge that a storage limit for embryos destined for treatment is useful in practice and we are persuaded by the reasons for increasing the storage limit to ten years. In relation to gametes or embryos created for or donated for research, we are less persuaded by the argument that these, too, should be subject to a ten year time limit on storage. **We therefore recommend that, in relation to gametes or embryos created or donated for research, the ten year limit should either be extended or removed.**
250. **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.**

Register of Information

251. Clause 32 of the draft Bill proposes a series of new provisions to replace existing section 31 of the 1990 Act requiring the HFEA to keep a register of information. Clause 33 allows the Secretary of State to make regulations requiring or regulating the disclosure of otherwise confidential information for medical research purposes. We have dealt below with those provisions on which we received substantive evidence.

New section 31ZA: access to the register for civil partners

252. Proposed new section 31ZA(2)(b) and (5) of the 1990 Act (in clause 32) extends the current provisions, enabling an applicant to find out whether they are related to a person with whom they propose to marry, to those intending to enter a civil partnership.
253. The Government's motivation is to update the 1990 Act in line with civil partnership legislation. The current provisions are principally designed to avoid consanguinity, but we recognise that for those entering a civil partnership the issue is more likely to be avoiding incest. Professor Almond found the provisions "puzzling" since the decision to introduce civil

¹³³ See also Ev06, para 13, Ev38, para 18, Ev36, para 6, Ev38, para 7.1, Ev48, para 9, Ev59, answer to Q14, QQ135–137, Q406

partnerships was made by Parliament on the basis that they were not the same as marriage. (Ev21, para 2.4.5)

254. Almost all of those who raised this provision supported it as far as it went, but most argued that access should be extended more generally beyond those planning to enter civil partnerships. For example, the HFEA noted that approximately 40% of children are now born to unmarried couples. They said there was “something rather old fashioned and inappropriate about limiting access to couples entering into formal legal arrangements” and argued that the provision should extend to all cohabiting couples or even to all donor-conceived people embarking on an intimate relationship. (Ev12(a), para 40) This position received much support.¹³⁴ The Donor Conception Network noted that other parts of the draft Bill recognised unmarried partners in the context of legal parenthood. (Ev31, para 12 and 14)
255. Although this was not raised by witnesses, we were concerned that wider access might put an administrative burden on the regulator. The HFEA noted that the Human Tissue Act 2004 contained a statutory definition of ‘partner’ which could be adopted to define increased access. (Ev12(a), para 40) Professor Brownsword argued that the registrar should have the discretion to resist vexatious or frivolous claims. (Q 56) Several witnesses were concerned that these provisions were silent on the consent requirements. The HFEA noted that there was no requirement for a joint application or for consent from the other person and argued that this appeared to create a right to access genetic information about a third party without their consent. Donor Conception Network also noted this “odd omission” and argued that consent should be required. (Ev31, para 13, 14)
256. We understand the Government’s logic in extending access provisions to those entering civil partnerships, but we are concerned that limiting access only to those entering civil partnerships misses many people who are entering (or planning to enter) intimate relationships and those who may be planning children outside marriage or civil partnership. **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.**

Section 31ZA (access to identifying information about genetic half-siblings)

257. Proposed new section 31ZA(2)(c) of the 1990 Act makes a new provision that a donor-conceived person aged 18 or over is entitled to request information about the number, sex and year of birth of their donor-conceived half siblings. New section 31ZD enables donor-conceived people to request and obtain identifying information about their genetic half-siblings.
258. Most witnesses welcomed these provisions.¹³⁵ However, the PGH Foundation were concerned that the provisions might vary or extend the duty of care owed by clinical geneticists to their clients and that the legal basis for disclosure was not clear cut. (Ev51, para 15(2) and (3)) Several witnesses argued that the provision should be extended: to people conceived as the result of surrogacy;

¹³⁴ Ev54, para 3.6, Ev25, para 15, Ev26, para 17, Ev37, para 3.7, Q56

¹³⁵ Ev54, para 2.4, Ev37, para 2.4, Ev29, para 2.4, Ev30, para 2.5

and to the descendants of donor-conceived people. (Ev54, para 3.5 and Ev31, para 7) We support the provisions in the draft Bill subject to the relevance, if any, of the Data Protection Act being taken into account.

Section 31ZE (voluntary contact register)

259. Proposed new section 31ZE provides the regulator with the power to set up or keep a voluntary contact register. This has been trialled by UK DonorLink and has been supported by several witnesses. (Ev54, para 2.6, Ev37, para 2.6) We also support this provision and **we recommend that the draft Bill be amended to allow the HFEA to set up a voluntary contact register.**

Use of information for research purposes

260. Clause 33 allows the Secretary of State to make regulations requiring or regulating the disclosure of otherwise confidential information for medical research purposes. Most witnesses supported these provisions, but raised concerns about safeguarding data and consent.¹³⁶ For example, the PHG Foundation supported “medical research using identifiable information from those registers ... subject to proportionate safeguards being taken and provided that disclosure is in the interests of improving patient care or is in the public interest”. (Ev51, para 15(1)) The HFEA welcome disclosure “with appropriate consent”. (Ev12(a), para 40) The BMA argued that much research could be undertaken using anonymous data and that the draft Bill should make it clear that section 33C should only be used where it was not possible to seek patient consent. (Ev07, paras 21 and 23) However, the Society for the Protection of Unborn Children (SPUC) argued that permission to disclose information for research purposes breaches the most basic of ethical principles. (Ev65) We support the provisions in the draft Bill subject to consent provisions being satisfactorily resolved.

Age of access

261. Access provisions in the draft Bill are limited to those aged 18 or over. We heard from many witnesses who argued that the age limit should be lowered. Most witnesses argued that the limit should be set at 16 rather than 18.¹³⁷ However, some witnesses argued that there should be no age limit in accessing information. For example, Tom Ellis, a donor-conceived person, argued that “Age 18 is too late. Developing human beings need access to their (genetic, biological) parents during the adolescent years when they are forming their own independent, individual identity.” (Ev16, para 15)¹³⁸ Andrew Bainham, Reader in Family Law and Policy at the University of Cambridge, noted that not all jurisdictions regard 18 as the appropriate age to access information. He suggested that in England ‘Gillick competence’ guidelines¹³⁹ could be used as a test, although he acknowledged that this could be problematic. (Ev14, para 15)
262. **We recommend that the age of access to the Register should be reduced to 16.**

¹³⁶ Ev09, para 15, Ev47, para 3, Ev07, para 21

¹³⁷ Ev23, para K, Ev25, para 15, Ev30, para 4.6, Ev31, para 19, Ev43, para 11, Q733

¹³⁸ See also Ev44

¹³⁹ ‘Gillick competence’ refers to guidelines approved by a majority in the House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority* (1986) 1 AC 112. Under the test, a doctor may give advice and treatment to a child under the age of sixteen in confidence and without the consent of the child’s parents if that child has sufficient maturity and intelligence to understand the nature and implications of the proposed treatment and provided that certain other conditions are satisfied.

CHAPTER 7: PART 3 (PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION) AND PART 4 (MISCELLANEOUS AND GENERAL) OF THE DRAFT BILL

Parenthood

263. Part 3 of the draft Bill seeks to take a new approach to parenthood, moving towards the concept of parenthood as a legal responsibility rather than a biological relationship. As Andrew Bainham, Reader in Family Law and Policy at the University of Cambridge notes, more children will have legal parents who are not also their biological parents and more ‘social parents’ will acquire the full status of legal parent automatically, as opposed to merely acquiring parental responsibility through legal process (Ev14, para 3). In particular:
- Clauses 42 and 43 replace provisions of the 1990 Act which enable an unmarried man to be the father of a donor-conceived child if he is ‘treated together’ with the mother in a licensed clinic. Clause 42 sets out circumstances in which a man is to be treated as the father of the child where agreed ‘fatherhood conditions’ apply. These ‘fatherhood’ provisions are set out in clause 43.
 - Clauses 48 to 50 amend section 28(2) and (3) of the 1990 Act to include the situation where one member of a female same-sex couple is treated with the consent of the other (whether or not they are civil partners), and would confer legal parenthood on the consenting partner.
 - Clause 60 extends the procedures under section 30 of the 1990 Act (which currently enables a commissioning married couple to acquire a ‘parental order’ in surrogacy cases) to civil partners and to unmarried commissioning couples whether of the opposite sex or the same sex.
264. This is an approach that has proved controversial and we have had a significant amount of evidence that is quite divided on the merits of this approach. Many witnesses gave general support to the Government’s approach towards legal parenthood and the benefits this would bring to the area of assisted reproduction.¹⁴⁰
265. We heard evidence of some specific concerns. Tom Ellis, a donor-conceived person, argued that a man or woman whose gametes are not used to create a child should be referred to not as a ‘parent’ but as an ‘adoptive parent’ or a ‘step-parent’. (Ev16, para 16) The HFEA were concerned that clauses 42 and 43 could allow a woman to ask her own father or brother to be the father of the child (Ev12(a), Appendix A). Brenda Almond, Emeritus Professor of Moral and Social Philosophy at the University of Hull, noted that although provisions had been put forward in the name of equality, the provisions were “couched entirely in terms of women”. (Ev21, para 2.2)
266. We also received much evidence from those opposed to the Government’s approach. For example, Professor Almond told us she found the proposals “confusing and ambiguous” and that in seeking to replace biological parenthood with a legal conception the Government “do not do this either overtly or consistently”. (Ev21, para 1.1) Others had a more ethical

¹⁴⁰ See also Ev51, para 16, Ev07, Ev29, para 2.1, Ev33, para 8, Ev38, para 8, Q413

objection: for example, the Christian Institute argued that the provisions were “a radical and dangerous new departure in family law” (Ev61, para 13) and the Family Education Trust were deeply concerned at the “lego-kit model of family construction” in the draft Bill. (Ev69, question 16(a)) CORE argued that it was hasty to push through such recommendations without proper discussion. (Ev79, para 5)¹⁴¹

Feelings of donor-conceived people

267. While the provisions of Part 3 take a legal approach to parenthood issues, we have sought to take into account a more human angle, including the views of donor-conceived people about parenthood. We were struck by the evidence from David Gollancz who told us that when he first spoke publicly about his experience of being donor-conceived “it was as though someone had taken my autobiography and torn it up”. (Ev44) We also heard oral evidence from Joanna Rose and had written evidence from several other donor-conceived people.

The right to know and the need to be told

268. The draft Bill does not provide a donor-conceived person with a legal right to be told that they were so conceived, but only the more limited right to inquire, once they reach the age of 18, whether this is the case (see Chapter 6). Neither does the draft Bill place legal parents under a duty to tell a child he or she was donor-conceived. Professor Almond argued that the parenthood provisions would create a sizeable minority of people legally and formally disadvantaged by being deprived of knowledge of their own genetic origins. (Ev21, para 2.1) Andrew Bainham noted that the provisions were similar to those in the Adoption and Children Act 2002 which do not give the adopted person the right to know that he or she is adopted but do give the right to access certain information at the age of 18, including the right to access his or her original birth certificate. (Ev14, para 5) We heard much powerful evidence on whether the draft Bill should provide a legal right for a donor-conceived person to know of his or her genetic parents.¹⁴²
269. Many of those who supported such a legal right did so on the basis that as the state was involved in assisted conception, it should not be actively involved in a deception. Walter Merricks, Chairman of the Donor Conception Network said that assisted conception was “licensed by the state and authorised by the state”. (Q 689) David Gollancz argued that “where the state intervenes ... it has a duty to protect that right not to be deprived or deceived” (Ev44). Similarly, Joanna Rose argued that “the more people who are complicit in that the worse.” She told us she felt that it was “an assault on somebody’s personhood to misinform them about their ancestry” and that “the Government’s responsibility [is] to lead the way in the right way to parent children and not to deceive them, and certainly not to be complicit in that”. (QQ 695, 696, 705)
270. Andrew Bainham told us that the draft Bill should be amended to give donor-conceived people the legal right to know and the legal parents the legal duty to tell because “the right to information at the age of eighteen is largely illusory in the case of donor-conceived children unless they know they are

¹⁴¹ See also Ev87, para 6, Ev63, Ev55, para 16, Ev62, Ev65, para 8.2, Ev78, Ev74, Ev24, para 16

¹⁴² Ev72, para 15, Ev87 para 6.4

donor-conceived”. He also noted that international law increasingly recognised that the child has a right to knowledge of biological origins and that there was a ‘very strong trend’ in English domestic law to get at the truth of biological origins. (Ev14, paras 5–9) He also noted that the draft Bill as it stands “is capable of discriminating in favour of the donor-conceived children in same-sex relationships and against those who have opposite-sex legal parents” because it becomes clear to the child of same-sex parents at an early age that those parents cannot both be the biological parents.

271. Several witnesses who did not necessarily support a legal right or duty, argued that parents of donor-conceived children should be open and honest. For example, Susan Golombok, Professor of Family Research and Director of the Centre for Family Research in the Faculty of Political Sciences, University of Cambridge, thought “it is better for children to be told, and if they are going to be told, they should be told as young as possible”. (Q 902)¹⁴³ Walter Merricks said that the driving philosophy of the Donor Conception Network was “that children who are conceived through donated gametes or embryos should be told the truth about the origins of their conception”. (Q 675) Some witnesses were firmly against making it a legal right or duty. For example, Dr Françoise Shenfield, Clinical Director in Obstetrics and Gynaecology, University College London Hospital Reproductive Medicine Unit, argued that it would be an “infringement of parental autonomy and responsibility”. (Ev105)
272. In keeping with our approach in paragraph 239 we believe that the rights of the child should always be taken into account. We have grappled with the questions of whether it is in the best interests of the child to tell them about their biological parents and who should decide this. We note that many of the provisions in Part 2 of the Bill are illusory if the fact of donor-conception is not known. We believe that it is in the best interests of the child to know of their donor conception. Parents should be encouraged to be open and honest, and counselling and intermediary services should be available to them. However, we do not support those who call for a statutory duty on parents to tell their child of his or her donor-conception.

Birth certificates

273. Related to the arguments about a legal right to know is the issue of what, if anything, should be registered on a donor-conceived child’s birth certificate. We heard a lot of evidence from those who supported the fact of donor-conception being noted on the birth certificate and from those who opposed such a move.
274. Those who argued in favour of registering the fact of donor conception on the birth certificate did so for a number of reasons. For example, Søren Holm, Professorial Fellow on Bioethics at Cardiff Law School, and Professor of Medical Ethics at the University of Oslo, told us that “fertility treatments have created a split between genetic/gestational and legal parent status. We have to decide which of these the birth certificate should reflect. My view is that it should reflect both” (Ev111). Tom Ellis, a donor-conceived person, argued that it “must be required to be indicated on the birth certificate” because a person must know they are donor-conceived (Ev16, para 19). Professor Almond argued in favour because it would “give a

¹⁴³ See also Ev103

parent strong motivation for finding a way to let the child know”. (Q 901) Others also gave general support.¹⁴⁴

275. However, we also heard from those who were against such proposals. The Donor Conception Network told us that “It is no way to force people to tell their children by putting it on the birth certificates” and also argued that the law would be evaded and “would lead to fewer people telling their child.” (QQ 676, 687) Laura Witjens, Chair of the National Gamete Donation Trust did not see the point of putting it on a birth certificate because it would force people to tell rather than feeling they have to tell because it is in the child’s interests. (Q 691) Sheila Pike from Sheffield Teaching Hospitals NHS Trust, and Kate Grieve from University Hospitals Coventry and Warwickshire NHS Trust, argued that birth certificates were about parental responsibility not genetic origins and that families should have freedom to manage information for themselves. (Ev22)¹⁴⁵
276. **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.**

Counselling/intermediary services

277. The 1990 Act is amended in several places in the draft Bill to cover a requirement for persons to be given “an opportunity to receive proper counselling” in circumstances of accessing the register to find information about donor-conceived siblings or genetic parents (new sections 31ZA and 31ZD in clause 32 of the draft Bill), and as part of the conditions for licences for treatment (new section 13(6), 13(6A) and new section 13A).
278. Most of those who gave evidence were concerned to ensure that such counselling and intermediary services were available and free at the point of delivery (for example, Ev22, para 11). Lady Julia Tugendhat, Vice-President of the British Association for Counselling and Psychotherapy told us that it would be easy to make a token gesture and say that counselling was necessary and argued that it really was important. The National Gamete Donation Trust argued that counselling should be made available to those who are informed that a donor-conceived person has requested identifying information about them. (Ev101, note 126–127–131) **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**

¹⁴⁴ See also Ev44 , Ev103

¹⁴⁵ See also Ev105, Ev108, Ev43

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.

308. 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.
309. 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”.
310. 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.
311. 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.
312. 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.
313. 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.
314. 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

Centre for Social Justice
Centre for Stem Cell Biology & Developmental Genetics
Christian Action Research & Education
Christian Institute
Christian Medical Fellowship
Church of England's Mission & Public Affairs Council
Church of Scotland, Church and Society Council
Comment on Reproductive Ethics
Simon Cooper
Michael G. H. Dillon
** Sir Liam Donaldson
** Donor Conception Network
Kevin F. Egan
Tom Ellis
Equality Network
Evangelical Alliance
Christopher Evans
Family Education Trust
* Tom Feilden
** Professor Simon Fishel
Donald Fleming
Gregory Fletcher
Free Church of Scotland
* Professor Sir Richard Gardner
* Professor Raanan Gillon
GlaxoSmithKline
David Gollanz
* Professor Susan Golombok
* Professor Neva Haites
** Professor John Haladane
* Mark Henderson
** Her Majesty's Government
** Professor Søren Holm
** Human Fertilisation & Embryology Authority
Human Genetics Alert
Human Genetics Commission
** Human Tissue Authority

- ** Infertility Network UK
Institute of Biomedical Science
Dr Peter James
Joint Ethico-Medical Committee of the Guild of Catholic Doctors and
the Catholic Union of Great Britain
Professor David A. Jones
- ** Professor Sir Ian Kennedy
- ** Mr Charles Kingsland
Lawyers' Christian Fellowship
Linacre Centre for Healthcare Ethics
- * Dr Gillian Lockwood
Logos Alive
- * Dr Robin Lovell-Badge
Professor Alison Macfarlane
Professor Colin McGuckin
Dr Alexina McWhinnie
Medical Ethics Alliance
- ** Medical Research Council and Wellcome Trust
- * Dr Stephen Minger
Mitochondrial Research Group
- * Dr David Morroll
Motor Neurone Disease Association
Multiple Sclerosis Society
Professor Alison Murdoch
Muscular Dystrophy Campaign
- ** National Gamete Donation Trust
National Infertility Awareness Campaign
Northeast England Stem Cell Institute
- ** Nuffield Council on Bioethics
Parkinson's Disease Society
- * Lord Patel
PHG Foundation
Mrs Francis Phillips
Sheila Pike and Kate Grieve
Progress Educational Trust
ProLife Alliance
- * Joanna Rose

- Royal College of Nursing
- ** Royal College of Obstetricians and Gynaecologists
 - ** Royal College of Pathologists and Royal College of Pathologists, Speciality Advisory Committee on Genetics and Clinical Embryology
- Royal College of Physicians
- Royal College of Physicians' Committee on Ethical Issues in Medicine
- Royal Society
- Rupert Rushbrooke
- Salisbury Fertility Centre
- * Dr Ian Sample
- Professor Neil Scolding
- Scottish Council on Human Bioethics
- Sense About Science
- Professor Sally Sheldon and Professor Stephen Wilkinson
- ** Dr Françoise Shenfield
 - * Professor Austin Smith
- Society for the Protection of Unborn Children
- Mrs S. Somerville
- South East Post Adoption Network
- Southern Cross Bioethic Institute
- Jennifer Speirs
- Christine Thurgood
- TUC
- UK DonorLink
- UK National Stem Cell Network
- * Fergus Walsh
- Christine Whipp
- Chris Wotherspoon

Evidence received by the Joint Committee but not printed can be inspected in the House of Lords Record Office (020 7219 2333), e-mail HLRO@parliament.uk

6. Should the regulatory body or bodies be allowed to make charges for licenses?

PART 2 of the Draft Bill

Definitions

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

7. (a) Do you agree with new definitions in the draft Bill of ‘embryo’, ‘egg’, ‘sperm’, ‘gamete’, ‘nucleus’? If not, how would you propose to amend them?
- (b) Should the Secretary of State have the regulation-making power to expand these definitions as proposed in the draft Bill?

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

The text of the draft Bill (particularly in clause 17 and Schedule 2) reflects the position in the Government’s White Paper that the creation of hybrid and chimera embryos in vitro is prohibited, but that a regulation-making power would allow Parliament to agree exceptions to that prohibition for research purposes.

On publication of the draft Bill, the Government announced that it now intends to accept (in part) the approach advocated by the Commons Science and Technology Select Committee, that legislation should provide for certain inter-species entities to be created for research purposes under licence by the Regulator within a 14-day limit. The Government proposes that the entities to be permitted should be limited to those listed in clause 17(2) inserted section 4A(5)(b) to (d) on page 9 of the draft Bill (see also paragraph 1.12 of the introduction to the draft Bill on page ix). This would exclude from the licensing regime “pure hybrids” as described in clause 17(2) inserted section 4A(5)(a) and (e) on pages 9 and 10.

The Science and Technology Committee, in its recent Report “Government proposals for the regulation of hybrid and chimera embryos”, goes further than the Government’s new position and recommends that legislation should be permissive and provide that “in general, the creation of all types of human-animal chimera or hybrid embryos should be allowed for research purposes” under licence by the Regulator (recommendations 22 and 26 on page 63 of that Report). Furthermore, the Committee recommended that licensing should not allow for the development of interspecies embryos past the 14-day limit unless proved necessary.

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

Research licences

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

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

Embryo testing and sex selection practices

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

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

Consent to storage and use of gametes and embryos

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

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

Treatment conditions

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

12. What are your views on the proposal in the draft Bill to remove from the existing conditions of treatment the requirement to take account of “the need of that child for a father” before treatment services can be provided?

Clause 21 also extends the requirement to take account of the welfare of the child to all treatment services (not just those currently covered by the 1990 Act) as a result of the European Tissue Directive.

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

Storage limits

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

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

Register of information and access to the Register

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

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

PART 3 of the draft Bill

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

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

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

PART 4 of the draft Bill and other provisions

Legislating for future scientific development

In certain places, the draft Bill seeks to legislate now to regulate future scientific developments that are necessarily uncertain. In particular, it seeks to make provision:

- (i) for Parliament to pass Regulations to allow relevant provisions of the Act to have effect in cases where an egg or an embryo has been created from mitochondrial material provided by 2 women (sometimes called “artificial gametes”) (clause 34); and*
- (ii) for Parliament to pass Regulations making the sale, supply and advertisement of sperm sorting kits an offence, if such kits are developed in the future (clause 65).*

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

Embryo transfer in treatment

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

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

Other issues

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

to research on embryos *per se*, but that it was important to preserve the special status of the embryo. It was important to consider how ethics could be maintained and supervised.

Phil Willis MP, Chairman, asked whether he felt there was a lack of an ethical framework in the draft Bill.

Rt Revd Dr Lee Rayfield, Bishop of Swindon, answered no, but said that there were some concerns, particularly around views coming from the Commons Science and Technology Committee, which were seen as pushing the ethics a long way down the line. Dr Rayfield stated that the burden being placed on one regulator under the RATE proposal was not practical. Dr Rayfield sat on an ethical authority which was an advisory Committee in relation to gene therapy. Tissues and embryos should be considered by two distinct bodies and there should also be another independent body which could provide support on the ethical side¹⁵⁴.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, highlighted the importance of fathers. The draft Bill should not remove but enhance the need for the father provision. Removal of the need for a father provision would endorse fatherlessness and sent the wrong messages.

Paul Tully, General Secretary, Society for the Protection of Unborn Children, said that the ethical basis of the draft Bill was lacking and that the special status of the embryo was not preserved. Embryos should be protected from the time of conception. There was no rationale for a gradualist approach.

Phil Willis MP, Chairman, sought clarification of whether this position entailed rejection of the principles of the Warnock report. **Paul Tully** said it meant rejecting the conclusions of the Warnock Report, but that the Warnock Report had acknowledged the “special status” of the human embryo.¹⁵⁵

Andrea Minichiello Williams, Public Policy Director, Lawyers Christian Fellowship, stressed the need for proper systems when issues under consideration essentially re-define humanity. In particular this referred to the regulation of inter-species embryos. The welfare of the child was of paramount importance. Ms Williams represented opposition to animal-human hybrids. **Josephine Quintavalle, Comment on Reproductive Ethics**, was in favour of absolute respect for the embryo. The problem was how the new types of embryo dealt with in the draft Bill were defined.

Phil Willis MP, Chairman, asked whether Ms Quintavalle understood the definitions in the Bill.

Josephine Quintavalle, Comment on Reproductive Ethics, answered no. She also raised the issue of women’s health in relation to assisted reproduction and mentioned the ‘Hands Off Our Ovaries’ campaign of which CORE is a member. She stated that she represented opposition to eggs being harvested for research purposes. The justification for using eggs for research had not been borne out. The 1990 Act made reference to the criteria of necessary and desirable.

Julia Millington, Political Director, ProLife Alliance, stated that she represented opposition to all experimentation on embryos. To deliberately create a life for experimentation was morally wrong.

¹⁵⁴ Additional note by the witness—we have a general concern that Utilitarian ethical views are dominating the thinking

¹⁵⁵ Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, CM 9314, p.63–11.1

Phil Willis MP, Chairman, asked whether this meant opposition to IVF.

Julia Millington, Political Director, ProLife Alliance, said that it was not opposition to IVF in principle, but that there was opposition to freezing embryos. The storage and destruction of embryos in the IVF process was problematic.

Professor Neil Scolding, University of Bristol, on behalf of the APPG Pro-life Group, stated that there was no new justification, since the original legislation in this area, for overriding the special status of the embryo. The original legislation had permitted experimentation for the development of therapies. In the case of the draft Bill there was not the same justification. The Bill would permit research on the basis of curiosity. Professor Scolding emphasised that there now existed strong alternatives to embryo experimentation. Embryonic stem cell science had moved forward and the material needed could now be made from adult stem cells by reliable but very new methods of artificial ‘de-differentiation’. This altered the whole perspective on embryo experimentation.

Sarah Veale, Head, Equality and Employment Rights Department, TUC, said that the TUC was a secular organisation, its membership comprised those of all faiths and none. The TUC had submitted evidence to the Warnock inquiry, which was lay evidence as the TUC did not have scientific expertise. The TUC supported work to aid fertility and inherited disorders. If this could be done without embryo testing that would be even better. The TUC also had a pro-choice policy and would oppose any attempts to reduce time limits on abortion when the Bill was in Parliament.

Phil Willis MP, Chairman, clarified that the subject of abortion was not within the remit of the Joint Committee’s inquiry.

Rachel Bell, Associate Director, BioCentre: Centre for Bioethics and Public Policy, explained that her organisation looked at the impact of emerging technologies and had commissioned a working group eight months ago to look at hybrid chimeras and human and non-human combinations. This reported a month ago and made twenty recommendations, some consistent and some inconsistent with the draft Bill. The main issue was the creation of human embryos for research purposed and the use of human and non-human biological material.

Dr Donald Bruce, Science, Religion and Technology Project, Church of Scotland, that the SRT project had developed policy through looking at ethical issues and technology such as cloning and stem cell research developed. He represented a view similar to the first speaker, which could be summarised as “no, unless”. In other words ‘no’ to embryo testing except under very specific circumstances. There was a sense that the special status of the embryo was under threat. It was necessary to allow for basic research but there was a question of what research was justifiable.

Dr Andrew Fergusson, Head of Communications, Christian Medical Fellowship, said that his organisation represented 5,000 British doctors and 1,200 medical students. Within this group there were a range of views but the majority were in favour of an absolutist position on the status of the embryo. A single cell embryo should be viewed as a human and afforded respect and protection. On the question of whether he was happy with the ethical framework in the draft Bill, he said he would pose the question: what *is* the ethical framework of the draft Bill? There was a pre-supposition built into the arguments on this issue that it necessarily entailed a war of Judaeo-Christian and Secular-Humanist world views.

Dr Andrew Fergusson, Head of Communications, Christian Medical Fellowship, noted that scientists and others remained unclear about the significance and effects of research in this field. This was not solely a quantitative debate. The debate had significant qualitative aspects and many different perspectives should be taken into account, including ethics and theology. There was no need to rush such an important decision.

Lord Winston commented that from the perspective of the Jewish faith, it was important to protect life at a somewhat later stage than the embryonic stage. Other faiths and cultures would have different perspectives. He asked how a pluralistic society should resolve such issues.

Dr Andrew Fergusson, Head of Communications, Christian Medical Fellowship, stated that if there was uncertainty, then the benefit of the doubt should be given and the cautious route taken.

Mr Doug Naysmith MP, thought it was possible and desirable to combine philosophy and science in a reasonable debate.

Dr Andrew Fergusson, Head of Communications, Christian Medical Fellowship, agreed that scientists needed to engage in philosophical debate.

Dr Donald Bruce, Science, Religion and Technology Project, Church of Scotland, commented that arguments for the creation and use of inter-species embryos had been made on the assumption that the entity was not deserving of respect. He stated that he was a member of the advisory group for the HFEA's consultation on the issue of inter-species embryos. He feared that the relevant provisions of the draft Bill would render the HFEA's consultation pointless. He did not understand the reasons for the Government's recent change of policy on this issue.

Rachel Bell, Associate Director, BioCentre: Centre for Bioethics and Public Policy, referred to page 13 of the recent report of the Centre for Bioethics and Public Policy. The definition set out in that report was produced before publication of the draft Bill. The relevant part of the report recommended that legislation should be clear as to whether particular entities were to be regulated under human or animal legislation.

Andrea Minichiello Williams, Public Policy Director, Lawyers Christian Fellowship, noted that whether the entity was classified as animal or human had wide legal ramifications. Inter-species embryos were banned in many countries including France, Germany, the Netherlands, Italy, Belgium, and Canada. In some of these countries scientists could be imprisoned for breaking these laws. Article 13 of the Council of Europe Convention on Human Rights and Biomedicine ruled out the creation of animal human hybrids for research purposes. Article 18 stated that where the law allows research on embryos *in vitro* it is necessary to ensure adequate protection for the embryo. The creation of human embryos for research purposes is prohibited. There was a risk that the UK would become ethically isolated and when legislating in this area, Parliament should bear in mind the international rule of law.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, stated that the potential of adult stem cell technology should be recognised. Researchers should move away from embryonic stem cells because their utility had not been demonstrated. On the other hand, patients had been successfully treated using adult stem cell technology. With only limited resources available, those resources should be targeted here. There was also an economic imperative which pointed in

with abortion, where some hospitals refused to tell parents the sex of their unborn child, because of the prevalence of abortion in some cultures when it was revealed that the child was a girl. There was concern at the destruction of embryos, and the resultant demographic problems that might ensue. She referred to the demographic problems apparent in India and China where there was a clear cultural preference for male children.

Phil Willis MP, Chairman asked if she was opposed to pre-implantation diagnosis, and whether it was better to implant an embryo with defects.

Julia Millington, Political Director, Pro-Life Alliance, answered yes.

Dr Ian Gibson MP asked participants what they thought about the human genome project.

Josephine Quintavalle, Comment on Reproductive Ethics, answered that we should learn to cure not kill.

Dr Ian Gibson MP asked participants what they thought about gene therapy.

Josephine Quintavalle, Comment on Reproductive Ethics, said that developments in the treatment of Parkinson's Disease were interesting. She said that the Committee should hear more about the alternatives—at the moment the approach seemed to be stem cells or nothing. Stem cell research was interminably linked in the public eye with embryos. *The Guardian* had recently run a story about cardiac treatment using bone marrow stem cells, and showed a picture of an embryo as an illustration. There was a need to look at other ways of doing things.

Paul Tully, General Secretary, Society for the Protection of Unborn Children, said that with regard to pre-implantation diagnosis, the draft Bill was headed in the direction of eugenics, as it was seeking to select out disabilities. From the point of view of people with such disabilities, this is seen as discrimination. Some people saw their disability as part of their personality. It was possible to treat some conditions after birth so that the disability element did not arise. Some disabled people saw screening as discrimination, as if to say “you are not welcome: embryos which are like you will be discarded”. It could be argued that scientists and embryologists were protecting themselves, because they did not want the bad publicity of the birth of children with disabilities, or for people to say it was their fault.

Phil Willis MP, Chairman said that Paul Tully had referred to the ‘wrong’ embryoid that mean there was a ‘right embryo’?

Paul Tully, General Secretary, Society for the Protection of Unborn Children, said he had used the phrase as a metaphor. He was not saying that able-bodied people were ‘superior’ in any way.

Lord Winston presented a scenario, which was based on a true circumstance, and was by no means unique. He referred to the case of a woman who had come to his clinic, who had a condition called Conradi Syndrome. This meant she had difficulty walking and keeping her balance. She didn't want her children to have the same lack of dignity that she had. Lord Winston asked how Mr Tully would respond to this scenario.

Paul Tully, General Secretary, Society for the Protection of Unborn Children, said he would refer her to previous advances in the treatment of medical conditions using ethically acceptable research methods. Regarding the example of Cystic Fibrosis—sufferers who might have once expected to live for 30 years, may now live for 60 years. It was desirable to give the patient hope.

Lord Winston said that there were 6,000 single genetic defects, and Cystic Fibrosis was an exception in that it could be treated. Many other conditions presented a scenario of declining health. Mr Tully was asked to respond.

Paul Tully, General Secretary, Society for the Protection of Unborn Children, referred to types of cancers that were untreatable in the past but were now treatable. Hope should not be denied because these conditions could be treated in the future.

Sarah Veale, Head, Equality and Employment Rights Department, TUC said that the TUC felt that the testing of embryos could be justified, but she found it difficult that a secular organisation such as the TUC might be accused of eugenics in making such an assertion, as if it would support the most horrendous examples of eugenics. In a society of checks and balances, this simply would not happen. The ban on sex selection for non-medical purposes should be retained. Ms Veale referred to the example of China as an illustration of why.

Phil Willis MP, Chairman asked if she was opposed to sex selection for family balancing purposes.

Sarah Veale, Head, Equality and Employment Rights Department, TUC said sex selection for family balancing purposes should not be allowed. She said that nature does a pretty good job on its own if you look at the statistics.

Dr Donald Bruce, Science, Religion and Technology Project, Church of Scotland said that the Church of Scotland did not have a formal view. In general he would wish to follow the Council of Europe Convention. Sex selection was acceptable in severe genetic cases, but not for family balancing or social reasons. Sex selection should only be permitted under exceptional or severe circumstances, but this raised the problem of how you define such circumstances. The question was at what point a line was crossed. But he argued that, once you accept one non-medical reason, you could argue that any non-medical reason could be justified, which could be dangerous.

Rt Revd Dr Lee Rayfield, Bishop of Swindon, largely supported Donald Bruce. To undertake sex selection against disease may not be a problem because was in itself a decision to alleviate suffering. He did not support sex selection for social reasons. The Church of England would support a careful case-by-case analysis of tissue typing of embryos. However, the HFEA had said it should only be undertaken as a last resort, and there was some slippage in language used in the draft Bill. Sex selection should be a last resort, and that the Bill as drafted would widen the door.

Dr Donald Bruce, Science, Religion and Technology Project, Church of Scotland said the Church of Scotland would oppose tissue typing if the discarded embryos were not diseased.

Andrea Minichiello Williams, Public Policy Director, Lawyers Christian Fellowship, expressed the wish that a disability group was represented. Even with society's checks and balances there were dangers. Society did not live with Down's Syndrome or Williams Syndrome in a way that it once did. This raised serious questions about the way human dignity is perceived, how we care for vulnerable people and how we perceive them.

Mr David Burrowes MP asked participants what they made of the scenario that Lord Winston had raised earlier.

Andrea Minichiello Williams, Public Policy Director, Lawyers Christian Fellowship, said that all funds and resources should be directed into cures.

to know who their biological parents were. The welfare of the child should be the top priority. The Adoption and Children Act stated that the welfare of the child should be paramount, and this draft Bill alters that.

Phil Willis MP, Chairman raised the question of donor-conceived people, asking if a record of their biological parenting should be placed on the birth certificate.

Rt Revd Dr Lee Rayfield, Bishop of Swindon, said that the Church of England had concerns around donor insemination, and would support people finding out who their biological father was. IVF had complicated how we related to people. In the example of a cytoplasmic hybrid embryo, its mother could be viewed as a sheep. As a result the world was fragmented.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, said that research demonstrated the importance of fathers, and therefore, rather than removing the provision, it should be made to work better. The provision as it stands was not that you couldn't have IVF without a father, but it flagged up their importance. The draft Bill proposal was counter-productive, especially when viewed against a recent Government consultation on promoting the parental responsibilities of absent fathers. The draft Bill was giving off a confused message and was wrong-headed. Reference was made to Clause 51 of the draft Bill, which states that no man is to be treated as the father of the child. This was extraordinary. Dr Boucher argued that, in the draft Bill as a whole, there was no balance between the rights of parents and the rights of children. Greater regard should be given to the most vulnerable. Being a parent was not a right. In terms of the provisions of the draft Bill on access to information, not allowing a donor-conceived child to know until they are 18 means they would be effectively fatherless throughout childhood. The proposal might be good from an equality point of view but was not good for the child.

Phil Willis MP, Chairman asked how he knew it damaged children.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, noted that a wealth of evidence pointed to the value of a father. Much of the research work undertaken on the children of same-sex parents looked at younger children, whilst there was little evidence concerning children in adolescence. In addition, the groups that have been studied are small. He argued that the birth certificate should have information in relation to biological parenting on it.

Phil Willis MP, Chairman, asked if Dr Boucher could provide them with the evidence he had referred to.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, noted that he had already done so in written evidence.

Lord Mackay of Clashfern commented that it had been suggested to the Committee that research that points to the value of a father is actually due to other factors, such as economic circumstances. He asked if Dr Boucher could identify any research that shows that the value of a father goes deeper than this.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE, said he would send a bibliography with relevant references to the Committee.

Lord Jenkin of Roding asked whether there should be a legal obligation on parents to tell their children about their biological heritage.

Dr Daniel Boucher, Director of Parliamentary Affairs, CARE suggested that details of biological parentage should be on the birth certificate. There should

family law and the meaning of humanity. It must be done, because so few people understood the implications of what the forum has discussed. The Committee should give proper consideration to this.

Phil Willis MP, Chairman thanked participants for attending, and closed the meeting.

as possible and require a full debate in Parliament every time!”¹⁵⁸ Three others supported this view by quoting it as their contribution to the topic comment thread.

7. Two people (5%) expressed support for doctors and patients together taking decisions about the use of embryos in fertility treatment, albeit with the use of external regulation or advice when required. Of these, one considered that the parents/mother and their/ her medical adviser(s) were “far more familiar with their personal circumstances than any legislator or quango could be and stand to be far more affected by the outcome”. External regulation should be required only where “there is serious possibility of harm to the resulting child or to any third party” (not including harm to the embryo).¹⁵⁹ Another suggested that “guidance derived centrally” could be used by doctors and their patients.¹⁶⁰
8. Four comments (10%) advocated a tiered approach, involving a combination of Parliament, the Regulatory Authority and doctors and patients. Of these, three proposed that Parliament should decide the principles on which decisions are based and enshrine them in law. The Regulatory Authority would have the power to take decisions. Complex cases could be referred by doctors to the Regulatory Authority for consideration, which could then be referred to a Parliament/Government committee for a decision.¹⁶¹ One person suggested that Parliament should set a broad framework for decision-making, including protection for viable embryos, and the rest should be determined by patients and doctors; and in addition proposed that the HFEA be abolished or overhauled to adopt a more patient and embryo-friendly approach.¹⁶²
9. Four contributors (10%) specifically objected to doctors being given responsibility for taking decisions on the use of embryos in fertility treatment. One contributor said that as a medical doctor himself, he did “not want to shoulder this responsibility”.¹⁶³ Others suggested that individual doctors have “no more expertise in moral decision making than anyone else”, and that the “wider implications of these decisions are too big to be left to parents and doctors with vested interests”.¹⁶⁴
10. No contributors advocated that the Regulatory Authority alone should be responsible for taking decisions on this issue. Five people specifically objected to this idea (13%). Their reasons for doing so included the suggestion that the Regulator is not sufficiently accountable and that an unelected body should never take such decisions.¹⁶⁵ A medical doctor expressed “grave concerns” about the people appointed to bodies such as the HFEA and did not want them to have more power.¹⁶⁶
11. One contributor proposed that a referendum be called to allow the public to decide on the issue.¹⁶⁷

¹⁵⁸ james2007, 20 June

¹⁵⁹ CGavaghan, 25 June

¹⁶⁰ Maoldhomhnaigh, 25 June

¹⁶¹ Mattws1, 23 June; amw67, 25 June;

¹⁶² Tony35, 26 June

¹⁶³ Sam51, 26 June

¹⁶⁴ John, 21 June; eh, 21 June

¹⁶⁵ gsmith, 20 June; ski1966, 21 June; fhs, 26 June

¹⁶⁶ Sam51, 26 June

¹⁶⁷ Eh, 21 June

“The regulatory bodies have not proved themselves to be independent and this sort of authority cannot be passed to an unelected, unrepresentative body.”¹⁸²

25. A researcher in embryology wrote that the regulation of research is extremely burdensome to researchers and slows progress dramatically. The submission considered that the Regulatory Authority should not have the right to regulate on all aspects of interspecies embryo research. He/she advocated that total or partial hybrids and chimeras be banned by Parliament to ease the burden of regulation. The local research ethics committee (LREC) system could have a greater role and the Regulatory role be reduced to a legal oversight/LREC advisory function.¹⁸³
26. Three contributors (7%) considered that Parliament should have a direct role in making decisions in this area, without delegating to the Regulatory Authority. Their reasons included the need for accountability through an elected decision-making body and the wish that Parliament retain control of the Regulatory Authority to ensure that all decisions are ethical.¹⁸⁴
27. Four people (10%) considered that Parliament’s role should be to legislate against the creation of hybrid embryos altogether.¹⁸⁵
28. A total of 38 of the 42 comments (90%) raised objections to the creation of hybrid embryos altogether. Several did so on the basis of religious, ethical or moral convictions, regarding it as “contrary to human dignity”¹⁸⁶, “wrong and unethical” to use human embryos as a “means to an end”¹⁸⁷, or attempting to “play God”¹⁸⁸.
29. Two suggested that creating human/animal hybrids went against the Warnock Review principle that the human embryo should be afforded special status.¹⁸⁹ Eight contributors considered the creation of hybrid embryos unnecessary for research purposes:
- “why is hybridisation necessary for research when there is evidence now that an ethical source of stem cells, adult stem cells, have been utilised successfully in treatments?”¹⁹⁰
- “Animal/human hybrid embryos are alleged to be needed to conduct embryonic stem cell research but adult stem cell research has far greater potential to create useful therapies and is ethically sound.”¹⁹¹

¹⁸¹ Paul john, 24 June

¹⁸² Jarmum, 19 June

¹⁸³ M, 20 June

¹⁸⁴ Pierrekirk, 23 June; John Paul, 24 June; TeJulyan, 22 June

¹⁸⁵ James2007, 20 June; Thomas, 25 June; Sam51, 26 June; fhs, 26 June.

¹⁸⁶ AD50, 22 June

¹⁸⁷ AlanTheLionHeart, 15 June

¹⁸⁸ Sedals55, 16 June

¹⁸⁹ Jarmum, 19 June; fhs, 26 June

¹⁹⁰ ethiclar,29, 15 June

¹⁹¹ Watson, 25 June

15. Paragraph 71 of the memorandum explains that the power will enable testing for new purposes that may be developed in the future to be regulated. The power may be used to add to, or remove from, the list of permitted purposes or alter the restrictions in paragraph 1ZA(2) to (5). This power is not inappropriately wide in principle but, if there are any particular ways in which Parliament would not wish the power to be exercisable, those ways should be specified in the bill, in addition to the restriction about sex selection on non-health grounds.

LORD SHAW OF NORTHSTEAD

13 June 2007

professional bodies¹⁹⁹ in correspondence with the Department as well as by the Science and Technology Committee in its Fifth Report of Session 2004–05²⁰⁰.

In the light of all the evidence we took the view that a single regulatory body, with high-level expert advisory panels established by statute and with a clear remit, and working under a flexible framework established by Parliament, would be the best approach to regulation in this area. This model recognises the need to harmonise regulation in order to ensure consistency across the whole sector, while avoiding the potential for gaps, such as those discussed recently in respect of stem-cells, to appear in regulation.

The use of expert advisory panels would also meet any criticism that the advice received by the Authority was partial and not transparent.

It also recognises the direction taken by the EU in its Directives concerning standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; and blood. These Directives cover the whole range of issues to be regulated by RATE and, in our view, it would be disproportionate to maintain three competent authorities when regulating across similar sectors.

Certainly, if we did not already have the HFEA, HTA and MHRA in place as competent authorities and were faced now with the Tissue and Blood Directives, we would be unlikely to be proposing the establishment of three authorities to deal with their subject-matter.

We do note the concerns that have been raised as to the remit of RATE and whether this would be too wide for a single authority. However, we take the view that RATE would be established, primarily, to regulate tissue, albeit a range of tissue in various circumstances. As I have mentioned above, the model we have proposed for RATE, involving a smaller board containing both professional and lay expertise and with advice being available to it from expert panels, is one that has been adopted successfully elsewhere.

I attach for the committee's information a table at Annex C [submitted but not printed] that sets out details of a number of bodies with the same or a similar configuration and each with a much wider remit than that proposed for RATE.

Some of these bodies, such as OFCOM, were the result of mergers of smaller organisations and your Committee may be interested in the merger into OFCOM which has been audited by the NAO²⁰¹. According to the NAO Report, published in July 2006, the main drivers for creating a single regulatory body were to respond to rapid change and ongoing technological development, to remove overlap of existing regulation; and to incorporate EU obligations. The NAO found that

¹⁹⁹ The Wellcome Trust, Medical Research Council and Academy of Medical Sciences in their letter of 12 October 2006 in which they said "The HFEA has already struggled to keep up with its remit under the [1990 Act] and has often been criticised for not having the breadth of expertise to deal with the relevant issues facing it. The HTA also appears to struggle with the difficulties of dealing with such a broad range of sectors and activities." Also, the Royal College of Nursing, Royal College of Obstetricians and Gynaecologists and the British Medical Association, in an undated letter to the Department late 2006 in which they said: "Both the HFEA and the HTA have found it difficult to ensure that they have the necessary range of expertise to make informed and appropriate decisions on matters that have a serious impact on the lives of many people."

²⁰⁰ —extract reproduced at Annex B [submitted but not printed]

²⁰¹ The creation of Ofcom: Wider lessons for public sector mergers of regulatory agencies: Report by the Comptroller and Auditor General | HC 1175 Session 2005–2006 | 5 July 2006—available at: http://www.nao.org.uk/publications/nao_reports/05-06/05061175.pdf

UK but including the EEA/EFTA countries) the majority—27—appear to have only one competent authority. However, as mentioned above, this is a developing area of regulation and we remain in close contact with competent authorities throughout Europe.

I do hope your committee finds this information useful.

CAROLINE FLINT MP

MINISTER OF STATE FOR PUBLIC HEALTH

27 June 2007

approach is that neither embryos under section 4(A)(5)(e) nor ‘true’ hybrids under section 4(A)(5)(a) would be allowed unless affirmative regulations under the proposed new paragraph 3(3) of Schedule 2 to the 1990 Act (introduced by paragraph 6 of Schedule 2 to the draft Bill) provided for their creation to be authorised by research licence in the light of evidence of the need for it.

7. An exception to this is the mixing of human sperm with a hamster’s egg for the purpose of testing the fertility or normality of the sperm up to the two-cell stage. This is allowed under the Human Fertilisation and Embryology Act and is the position the draft Bill maintains.
8. As the committee will be aware, an alternative approach to allowing on the face of the Bill the reatocn and use of inter-species embryos to be authorised by research licence would be for regulations under the new paragraph 3(3) of Schedule 2 to provide for it.
9. We are asking Departmental lawyers and Parliamentary counsel to produce revised draft clauses for the approach we have in mind, which we will provide to the committee as soon as they are available.
10. As indicated in the draft Bill command paper, we very much welcome the committee’s views. For example, whether the description of inter-species embryos at clause 17 captures the right type of entities appropriately; whether the proposed balance between allowing their creation on the face of the Bill or through regulations is right; and whether the Bill contains sufficient flexibility and future-proofing powers. We would appreciate any suggestions for any alternative approaches they may wish to recommend.

MR TED WEBB

DEPUTY DIRECTOR SCIENTIFIC DEVELOPMENT AND BIOETHICS

DEPARTMENT OF HEALTH

12 June 2007

The declarations of relevant interests are made:

David Burrowes MP declared an interest in having an intern provided by the Christian charity, CARE.

Dari Taylor MP declared an interest as Chair of the All-Party Parliamentary Group on Infertility.

Baroness Deech declared an interest as former chair of the Human Fertilisation and Embryology Authority 1994–2002; as former *ex officio* member of the Human Genetics Commission 1999–2002; as giving occasional lectures on infertility, stem cells and related issues for small honorarium and fare; and as writing a book on the development of infertility issues.

Lord Mackay of Clashfern declared an interest as Honorary Fellow of the Royal College of Obstetricians and Gynaecologists; as Patron of the Lawyers' Christian Fellowship and number of various Christian organisations; as Honorary Fellow of Royal College of Surgeons of Edinburgh; as Honorary Fellow Royal College of Physicians of Edinburgh; and as having presented the Bill in the House of Lords that led to the 1990 Act.

Baroness Neuberger declared an interest as a former member of the Human Fertilisation and Embryology Authority 1991–1995 and its predecessor bodies; as a former member of Medical Research Council 1995–2000; and as a former member General Medical Council 1993–2001.

Lord Turnberg declared an interest as a scientific advisor to the Association of Medical Research Charities.

Lord Winston declared an interest as Member, Scientific Advisory Committee, Association of Medical Research Charities; and as holding a licence to do research under the HFEA and as the director and shareholder of a company which does adult stem cell research.

It is moved that Phil Willis MP do take the Chair.—(*Lord Mackay of Clashfern*)

The same is agreed to.

The Orders of Reference are read.

The Joint Committee deliberate.

Ordered, That Professor Martin Johnson and Professor Sheila McLean be appointed as Specialist Advisers to assist the Committee.

Ordered, That the Joint Committee be adjourned to Tuesday 22 May at 1 o'clock.

Tuesday 22 May 2007

Present:

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|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Mackay of Clashfern | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Ms Dari Taylor MP |
| Baroness Neuberger | |
| Lord Selsdon | |
| Lord Turnberg | |
| Lord Winston | |

Robert Key MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 15 May are read.

The Joint Committee deliberate.

Ordered, That memoranda submitted to the Joint Committee be published.

Ordered, That the uncorrected transcripts of evidence given, unless the Committee otherwise order, be published on the internet.

Ordered, That the Joint Committee be adjourned to Tuesday 5 June at 1 o'clock.

Tuesday 5 June 2007

Present:

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| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Jenkin of Roding | Dr Ian Gibson MP |
| Baroness Neuberger | Robert Key MP |
| Lord Selsdon | Chris Mole MP |
| Lord Turnberg | Dr Doug Naysmith MP |
| Lord Winston | Geraldine Smith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 22 May are read.

Ordered, That Memoranda numbers HTEV1–4, 7 and 8 submitted to the Joint Committee be reported to the House of Commons for publication on the internet.

The Joint Committee deliberate.

The following witnesses are examined:

Professor Colin Blakemore, Chief Executive Officer, Medical Research Council; Professor Roger Brownsword, Professor of Law, King's College London; Hugh Whittall, Director, Nuffield Council on Bioethics; Vivienne Nathanson, Director of Professional Activities, and Dr Tony Calland, Chairman, Medical Ethics Committee, British Medical Association; Professor Peter Braude, Head, Department of Women's Health, King's College London and Chair, Scientific Advisory Committee, Royal College of Obstetricians and Gynaecologists; Dr Suzannah Lishman, Assistant Registrar, Royal College of Pathologists.

Ordered, That the Joint Committee be adjourned to Wednesday 6 June at 3 o'clock.

Wednesday 6 June 2007

Present:

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|-----------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Lord Jenkin of Roding | Ms Katy Clark MP |
| Baroness Neuberger | Dr Ian Gibson MP |
| Bishop of St Albans | Robert Key MP |

Lord Selsdon
Lord Winston

Dr Doug Naysmith MP
Chris Mole MP
Geraldine Smith MP

Phil Willis MP in the Chair

The Order of Adjournment is read.

The Joint Committee deliberate.

The following witnesses are examined:

Shirley Harrison, Chair, HFEA and HTA; Angela McNab, Chief Executive, HFEA; Adrian McNeil, Chief Executive, HTA; Sir Liam Donaldson, Chief Medical Officer; Mr Edward Webb, Director, Scientific Development and Bioethics, Department of Health; and Mr Christopher Cox, Bill Team Leader, Department of Health.

Ordered, That the Joint Committee be adjourned to Tuesday 12 June at 1 o'clock.

Tuesday 12 June 2007

Present:

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|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Jenkin of Roding | Dr Ian Gibson MP |
| Lord Mackay of Clashfern | Robert Key MP |
| Baroness Neuberger | Chris Mole MP |
| Lord Winston | Dr Doug Naysmith MP |
| | Geraldine Smith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 5 and Wednesday 6 June are read.

The Joint Committee deliberate.

The following witnesses are examined:

Dr Ian Sample, Science Correspondent, The Guardian; Fergus Walsh, Medical Correspondent, BBC; Tom Feilden, Science Correspondent, BBC Radio 4 Today Programme; and Mark Henderson, Science Editor, The Times.

Ordered, That the Joint Committee be adjourned to Wednesday 13 June at 3 o'clock.

Wednesday 13 June 2007

Present:

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|----------------------------|------------------|
| Baroness Deech | Ms Katy Clark MP |
| Baroness Hollis of Heigham | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Robert Key MP |
| Lord Mackay of Clashfern | Chris Mole MP |

Baroness Neuberger
 Bishop of St Albans
 Lord Selsdon
 Lord Turnberg
 Lord Winston

Dr Doug Naysmith MP
 Geraldine Smith MP
 Ms Dari Taylor MP

Phil Willis MP in the Chair

The Order of Adjournment is read.

Ordered, That Memoranda numbers HTEV05, 10–18, 20 and 21 submitted to the Joint Committee be reported to the House of Commons for publication on the internet.

The Joint Committee deliberate.

The following witnesses are examined:

Dr Mark Hamilton, Chair, British Fertility Society; Dr Dave Morroll, Chair, Association of Clinical Embryologists; Lady Julia Tugendhat, Vice President, British Association for Counselling and Psychotherapy; Professor Simon Fishel, Managing Director, CARE Fertility group; Charles Kingsland, Consultant Gynaecologist, Clinical Director, Hewitt Centre Liverpool; and Dr Gillian Lockwood, Medical Director, Midland Fertility Services.

Ordered, That the Joint Committee be adjourned to Tuesday 19 June at 1 o'clock.

Tuesday 19 June 2007

Present:

Baroness Deech
 Baroness Hollis of Heigham
 Lord Jenkin of Roding
 Lord Mackay of Clashfern
 Baroness Neuberger
 Lord Selsdon
 Lord Winston

Mr David Burrowes MP
 Robert Key MP
 Chris Mole MP
 Dr Doug Naysmith MP
 Geraldine Smith MP
 Ms Dari Taylor MP

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 12 and Wednesday 13 June are read.

Ordered, That Memoranda numbers HTEV22–41 submitted to the Joint Committee be reported to the House of Commons for publication on the internet.

The Joint Committee deliberate.

The following witnesses are examined:

Caroline Flint MP, Minister of State for Public Health; Edward Webb, Branch Head of Scientific Development and Bioethics, Department of Health, and Gareth Jones, Director of Scientific Development, Department of Health.

Ordered, That the Joint Committee be adjourned to Wednesday 20 June at 3 o'clock.

Wednesday 20 June 2007

Present:

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|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Robert Key MP |
| Lord Mackay of Clashfern | Chris Mole MP |
| Bishop of St Albans | Geraldine Smith MP |
| Lord Selsdon | Ms Dari Taylor MP |
| Lord Winston | |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The Joint Committee deliberate.

The following witnesses are examined:

Dr Robin Lovell-Badge, Head of the Division of Stem Cell Biology and Developmental Genetics, MRC National Institute for Medical Research; Dr Stephen Minger, Director, Stem Cell Biology Laboratory, Wolfson Centre for Age-Related Disease, King's College London; Professor Neva Haites, Chair, HFEA Scientific and Clinical Advances Group and Professor in Medical Genetics, University of Aberdeen; Clare Brown, Chief Executive, Infertility Network UK; Laura Witjens, Chair, National Gamete Donation Trust; Walter Merricks, Founder Member and Treasurer, Donor Conception Network; and Joanna Rose, a donor-conceived person.

Ordered, That the Joint Committee be adjourned to Tuesday 26 June at 1 o'clock.

Tuesday 26 June 2007

Present:

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|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Robert Key MP |
| Lord Jenkin of Roding | Chris Mole MP |
| Lord Mackay of Clashfern | Dr Doug Naysmith MP |
| Baroness Neuberger | Ms Dari Taylor MP |
| Bishop of St Albans | |
| Lord Selsdon | |
| Lord Winston | |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 19 and Wednesday 20 June are read.

The Joint Committee deliberate.

The following witnesses are examined:

Professor Sir Ian Kennedy, Healthcare Commission; Professor Sir Richard Gardner, University of Oxford; Dr Françoise Shenfield, University College

London Hospital; Professor Raanan Gillon, Emeritus Professor of Medical Ethics, Imperial College London; Professor Søren Holm, Cardiff Law School; and Professor John Haldane, Professor of Philosophy and Director, Centre for Ethics, Philosophy and Public Affairs in the University of Andrews.

Ordered, That the Joint Committee be adjourned to Wednesday 27 June at 3 o'clock.

Wednesday 27 June 2007

Present:

| | |
|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Mackay of Clashfern | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Robert Key MP |
| Baroness Neuberger | Chris Mole MP |
| Bishop of St Albans | Dr Doug Naysmith MP |
| Lord Selsdon | |
| Lord Winston | |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The Joint Committee deliberate.

The following witnesses are examined:

Professor Susan Golombok, Cambridge University; Professor Brenda Almond, Emeritus Professor of Moral and Social Philosophy, University of Hull; Professor Ann Buchanan, University of Oxford; Simon Denegri, Chief Executive, Association of Medical Research Charities; Professor Martin Bobrow, Chair, Hybrid/Chimera Embryos Working Group, Academy of Medical Sciences; Professor Austin Smith, Director, Wellcome Trust Centre for Stem Cell Research, University of Cambridge; Baroness Kennedy of the Shaws, Chair, Human Genetics Commission; and Lord Patel.

Ordered, That the Joint Committee be adjourned to Wednesday 27 June at half-past 6 o'clock.

Wednesday 27 June 2007

Present:

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|--------------------------|----------------------|
| Lord Jenkin of Roding | Mr David Burrowes MP |
| Lord Mackay of Clashfern | Dr Ian Gibson MP |
| Bishop of St Albans | Robert Key MP |
| Lord Selsdon | Chris Mole MP |
| Lord Winston | Dr Doug Naysmith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

A discussion was held with:

The Rt Revd Dr Lee Rayfield, Bishop of Swindon, Church of England; Dr Donald Bruce, Science, Religion and Technology Project, Church of Scotland; Dr Daniel Boucher, Director of Parliamentary Affairs, CARE; Dr Andrew Fergusson, Head of Communications, Christian Medical Fellowship; Andrea Minichiello Williams, Public Policy Director, Lawyers Christian Fellowship; Rachel Bell, Associate Director, BioCentre: Centre for Bioethics and Public Policy; Paul Tully, General Secretary, Society for the Protection of Unborn Children; Josephine Quintavalle, Comment on Reproductive Ethics; Julia Millington, Political Director, Pro-Life Alliance; Professor Neil Scolding, University of Bristol, on behalf of the APPG Pro-life Group; Sarah Veale, Head, Equality and Employment Rights Department, TUC.

Ordered, That the Joint Committee be adjourned to Tuesday 3 July at 1 o'clock.

Tuesday 3 July 2007

Present:

| | |
|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Jenkin of Roding | Dr Ian Gibson MP |
| Lord Mackay of Clashfern | Robert Key MP |
| Baroness Neuberger | Chris Mole MP |
| Lord Selsdon | Dr Doug Naysmith MP |
| | Geraldine Smith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 26 and Wednesday 27 June are read.

The Joint Committee deliberate.

Ordered, That the Joint Committee be adjourned to Wednesday 4 July at 3 o'clock.

Wednesday 4 July 2007

Present:

| | |
|--------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Lord Jenkin of Roding | Dr Ian Gibson MP |
| Lord Mackay of Clashfern | Robert Key MP |
| Baroness Neuberger | Chris Mole MP |
| Lord Selsdon | Dr Doug Naysmith MP |
| Lord Winston | Geraldine Smith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The Joint Committee deliberate.

Ordered, That the Joint Committee be adjourned to Tuesday 17 July at 1 o'clock.

Tuesday 17 July 2007

Present:

| | |
|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Ms Katy Clark MP |
| Lord Jenkin of Roding | Dr Ian Gibson MP |
| Lord Mackay of Clashfern | Robert Key MP |
| Baroness Neuberger | Chris Mole MP |
| Lord Selsdon | Dr Doug Naysmith MP |
| | Ms Dari Taylor MP |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 3 and Wednesday 4 July are read.

Ordered, That Memoranda numbers HTEV05(b), 06, 09, 09(a), 11(a), 12(a), 19, 36, 38, 41–115 and 84(a) submitted to the Joint Committee be reported to the House of Commons for publication on the internet.

The Joint Committee deliberate.

Ordered, That the Joint Committee be adjourned to Wednesday 18 July at 3 o'clock.

Wednesday 18 July 2007

Present:

| | |
|----------------------------|----------------------|
| Baroness Deech | Mr David Burrowes MP |
| Baroness Hollis of Heigham | Dr Ian Gibson MP |
| Lord Jenkin of Roding | Robert Key MP |
| Lord Mackay of Clashfern | Chris Mole MP |
| Baroness Neuberger | Dr Doug Naysmith MP |
| Bishop of St Albans | Geraldine Smith MP |
| Lord Selsdon | Ms Dari Taylor MP |
| Lord Winston | |

Phil Willis MP in the Chair

The Order of Adjournment is read.

The Joint Committee deliberate.

Ordered, That the Joint Committee be adjourned to Tuesday 24 July at 1 o'clock.

Tuesday 24 July 2007

Present:

| | |
|----------------------------|------------------|
| Baroness Deech | Dr Ian Gibson MP |
| Baroness Hollis of Heigham | Robert Key MP |
| Lord Mackay of Clashfern | Chris Mole MP |

Baroness Neuberger
Bishop of St Albans
Lord Winston

Dr Doug Naysmith MP

Phil Willis MP in the Chair

The Order of Adjournment is read.

The proceedings of Tuesday 17 and Wednesday 18 July are read.

The Joint Committee deliberate.

A draft Report is proposed by the Chairman.

It is moved that the draft Report before the Committee be read.

The same is agreed to.

Paragraphs 1 to 292 are agreed to, with amendments.

The Abstract is agreed to.

The Committee agreed that the summary of recommendations appear at the end of the report.

The Appendices to the Report are agreed to.

The Committee agreed that the draft Report, as amended, be the report of the Joint Committee.

Ordered, That certain papers be appended to the Minutes of Evidence.

Ordered, that the provisions of Standing Order 134 (Select Committee Reports) of the House of Commons apply to the report.

Ordered, That the Chairman make the report to the House of Commons and Lord Mackay of Clashfern make the report to the House of Lords.