

House of Commons

Science and Technology
Committee

**DEVELOPMENTS IN
HUMAN GENETICS AND
EMBRYOLOGY**

Fourth Report of Session 2001–02

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EMBRYOLOGY**

Fourth Report of Session 2001–02

*Report, together with
Proceedings of the Committee,
Minutes of Evidence and Appendices*

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Contacts

All correspondence should be addressed to The Clerk of the Science and Technology Committee, Committee Office, 7 Millbank, London SW1P 3JA. The telephone number for general inquiries is: 020-7219-2794; the Committee's e-mail address is: scitechcom@parliament.uk.

Footnotes

In the footnotes of this Report, references to oral evidence are indicated by 'Q' followed by the question number. References to written evidence are indicated by the page number as in 'Ev 12'.

TABLE OF CONTENTS

	<i>Page</i>
REPORT	
Introduction	5
Organisations and their structures	6
Human Fertilisation and Embryology Authority	6
Background	6
Income and expenditure	6
Performance	7
Human Genetics Commission	8
Background	8
Funding and activities	8
Advisory and regulatory framework	9
Stem cells	9
International perspectives	11
Legislative framework	11
LIST OF RECOMMENDATIONS AND CONCLUSIONS	14
PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT	16
LIST OF WITNESSES	17
LIST OF APPENDICES TO THE MINUTES OF EVIDENCE	17
MINUTES OF EVIDENCE	Ev 1
APPENDICES TO THE MINUTES OF EVIDENCE	Ev 11

FOURTH REPORT

The Science and Technology Committee has agreed to the following Report:

DEVELOPMENTS IN HUMAN GENETICS AND EMBRYOLOGY

Introduction

1. Our Committee has taken a long-standing interest in medical genetics research and its application. Our predecessor Committee's 1995 Report on *Human Genetics: the Science and its Consequences* followed an extensive and wide-ranging inquiry and anticipated many of the issues that lay ahead in this field.¹ In 2001 our predecessors reported on *Genetics and Insurance*, recommending a moratorium on the use of positive genetic tests by insurers and highlighting a number of problems with the existing regulatory framework in this area.² Their 2001 report on *The Scientific Advisory System* discussed the role of the Human Genetics Commission (HGC) as part of a wider examination of government scientific advisory committees.³ In March 2002 we held a seminar with leading researchers in the fields of embryology and stem cell research to discuss the policy and regulatory implications of recent advances of research using embryos.⁴ It is our intention to monitor developments in this area over the course of the Parliament.

2. On 24 April 2002 we took oral evidence from Dame Ruth Deech, former Chair of the Human Fertilisation and Embryology Authority (HFEA), Helena Kennedy (Baroness Kennedy of the Shaws), Chair of the HGC, and Suzi Leather, Chair of the HFEA. Dame Ruth, a family and property lawyer, was Chair of the HFEA from 1994 to 2002. She was replaced in April 2002 by Ms Leather, who has a background in consumer representation on health, food and agricultural issues and is also Deputy Chair of the Food Standards Agency. Baroness Kennedy is a criminal lawyer and has chaired the HGC since its foundation in December 1999. The transcript of this evidence session is printed with this Report, together with supplementary evidence provided by the HFEA, Professor Robin Lovell-Badge, from the National Institute for Medical Research, Dame Anne McLaren from the Wellcome Trust/Cancer Research UK Institute of Cancer and Developmental Biology and Professor Austin Smith from the Centre for Genome Research at Edinburgh University.⁵

3. This short Report draws attention to particular areas of concern raised by the witnesses, follows up on issues raised by inquiries from our predecessor Committees and makes recommendations to Government where action is urgently needed. Later this year the Government will publish its Green Paper on Genetics, to examine "the ethical, clinical, scientific and economic issues" surrounding genetics.⁶ **We welcome the intended breadth of the forthcoming Green Paper on Genetics and hope it embraces the views we express in this Report.**

¹ Third Report of the Science and Technology Committee, Session 1994-95, *Human Genetics: the Science and its Consequences*, HC41-I

² Fifth Report of the Science and Technology Committee, Session 2000-2001, *Genetics and Insurance*, HC 174

³ Fourth Report of the Science and Technology Committee, Session 2000-2001, *The Scientific Advisory System*, HC 257

⁴ This took place on 13 March 2002. The Committee heard from Dame Anne McLaren, Cambridge University; Professor Austin Smith, Edinburgh Centre for Genome Research; Professor Robin Lovell-Badge, National Institute for Medical Research; and Dr Alan Colman, PPL Therapeutics.

⁵ Ev 1-14

⁶ Speech by Rt Hon Alan Milburn MP, Secretary of State for Health, 19 April 2001

Organisations and their structures

Human Fertilisation and Embryology Authority

Background

4. The HFEA was established in 1991 by the Human Fertilisation and Embryology Act 1990.⁷ It is an executive non-departmental public body sponsored by the Department of Health and has a staff of around 30. No research on human embryos may be undertaken except under licence from the HFEA. It also licenses all UK treatment clinics offering in-vitro fertilisation or donor insemination, or storing eggs, sperm or embryos.

Income and expenditure

5. The HFEA generates income by charging fees to in-vitro fertilisation centres holding licences. It is set an expenditure limit (£1,575,000 in 2000-01). The Department of Health and the devolved administrations fund the difference between the levied charges (£1,242,000 in 2000-01) and this expenditure limit.⁸ The funding mechanism ensures that the HFEA's income remains the same whatever the income raised by fees, and therefore that it has no direct incentive to award licences. Given the importance of avoiding such an incentive, it is curious that the Department of Health has set a target for the HFEA to raise 70% of its income from fees. (In practice, it has exceeded this target: between 1994-95 and 2000-01 the HFEA raised 88% of its expenditure through fees, and in 1998 and 2000 made a profit.)⁹ The overall expenditure limit has presumably been set at the level the Department of Health thinks has been necessary for the HFEA, though how this figure has been reached is unclear.

6. Dame Ruth said that "If the HFEA were set up today, in the light of public fears about anything with the word "genetic" in it, whether it is BSE or genetically modified food or whatever, there would be a much more exhaustive approach. I believe that we have the least funding of any comparable organisation".¹⁰ Ms Leather said that when she saw the budget for the first time she "thought they had got the decimal point in the wrong place".¹¹ In June 2002, the HFEA issued a consultation document on its future funding.¹² It states that the HFEA needs "ongoing operating funding of at least £4.5 million" to perform its licensing and regulatory functions.¹³ (This is in addition to £3 million a year which it foresees will be needed for "information systems and accommodation".¹⁴) It cites scientific and clinical developments, public expectations and government policy as justifications for the increase. It states that the Department of Health has indicated that it will continue to provide £0.6 million baseline funding but that any increase in funding should come from licence fees.¹⁵ (It is not clear whether the HFEA will be subject to an expenditure limit in the future.) The HFEA sets out for consultation two alternative ways of raising the

⁷ See www.hfea.gov.uk

⁸ Ev 12-13

⁹ Income from licences issued for research is negligible (around £22,000). The HFEA is planning a consultation of the funding of its activities relating to research.

¹⁰ Q12

¹¹ Q14

¹² *HFEA Consultation on the Modernisation of Regulation and New Fee Strategy*, June 2002

¹³ *Ibid.*, para 61

¹⁴ *Ibid.*, para 62

¹⁵ *Ibid.*, para 61

funding of £4 million from fees. **The HFEA is asking for its income to be more than doubled. We accept that its activities have increased in recent years but, for such a large increase, it needs to make a more detailed financial case than its consultation document provides. If it can prove the need for such a large increase, it should be met by increased contributions from Government as well as from licensees. We are concerned that the Government's insistence that any increase in funding should be met from licence fees alone undermines the principle that the HFEA should have no incentive to award licences.**

Performance

7. The HFEA has been largely successful in ensuring public confidence in its regulation of fertility treatments and research. The Lords Stem Cell Research Committee reported that the HFEA is “highly regarded, both at home and abroad ... [and] has the full confidence of the scientific and medical research community”.¹⁶ We are unclear on what evidence it based this assertion. While many of its problems can be explained by a lack of funding, some criticisms can be levelled against the organisation. Professor Austin Smith, a stem cell researcher at Edinburgh University, has found the HFEA to be “inefficient ... and lacking in specialist knowledge” and “a slow and reactive” body. Professor Smith has found the issue of consent forms particularly problematic: “The HFEA provides no guidelines for drawing up consent forms for embryo donors and gives no advice to the licence applicant”.¹⁷ Dr Robin Lovell-Badge indicates that researchers have found the HFEA frustrating to deal with and that there has been criticism from researchers regarding the time the HFEA takes to process licence applications.¹⁸ Ms Leather said that the average time for research applications to be processed was four months.¹⁹ We have been told that some applications have taken a good deal longer than this. We note that in the year 2000-01 the HFEA missed its targets for licence renewal (for both treatment and research) by some margin, especially for research licences, though we recognise the problems it has had with high staff turnover.²⁰ **Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy.**

8. The HFEA's communication strategy seems to be focused on licensees and patients. While this may be in part because of a lack of resources, the HFEA does not appear to have made much effort to communicate more widely, yet the public has a legitimate interest in its work and administration. Until recently, the HFEA's website reflected poorly on the importance it attached to transparency and accessibility. The new-look site is a step in the right direction. The recently published Annual Report for 2000-01 said that the second quinquennial review of the HFEA recommended that it adopt “more open and transparent working practices”.²¹ Suzi Leather said that “communicating what we are doing, communicating what the possibilities of science are, what the benefits and disbenefits are, is probably the core challenge for the HFEA”.²² **The HFEA's new emphasis on communication with the public is welcome. Continued public confidence demands that the HFEA takes the lead in encouraging awareness and debate about research and treatment involving human embryos.**

¹⁶ House of Lords Stem Cell Research Committee, Session 2001-2002, HL 83(i), para 8.1

¹⁷ Ev 14

¹⁸ Ev 11

¹⁹ Q10

²⁰ Tenth Annual Report and Accounts 2001, HFEA, annex 6, p. 39

²¹ *Ibid.*, p.10

²² Q20

Human Genetics Commission

Background

9. The HGC was formed in 1999 as the result of a review of the advisory and regulatory framework for biotechnology conducted by the Office of Science and Technology and the Cabinet Office.²³ It took on the responsibilities of the former Advisory Committee on Genetic Testing, Advisory Group on Scientific Advances in Genetics and Human Genetics Advisory Commission.²⁴ The HGC is an advisory non-departmental public body under the Department of Health and Office of Science and Technology and has a secretariat of four drawn from these departments. Its brief is to analyse current and potential developments in human genetics and advise ministers; advise on strategic priorities in the delivery of genetic services by the NHS; advise on strategic priorities for research; and consult the public and other stakeholders and encourage debate on human genetic technologies.

Funding and activities

10. The HGC is funded by the Department of Health, with contributions from the Office of Science and Technology, National Assembly for Wales, Northern Ireland Assembly and the Scottish Executive. The HGC's total budget for 2000-01 was £425,000.²⁵ Our predecessor Committee recommended in 2001 that the Government should, with urgency, review the funding of the HGC.²⁶ The Government's response was disappointing, saying merely that it "is committed to keeping the resources available to all of its advisory bodies under review".²⁷ It is clearly a concern of Baroness Kennedy, who told us that "I am one of those people who, whenever I see a minister, never misses the opportunity of saying that we could do with more money".²⁸

11. Much of the HGC's non-staff expenditure goes on committees and public events. A vital part of the HGC's work is to engage the public in discussion about issues in human genetics. Its terms of reference state that it should "develop and implement a strategy to involve and consult the public and other stakeholders and encourage debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding". Baroness Kennedy told us that the HGC "did a consultation on the privacy issues around genetics and that cost us in the region of about £50,000".²⁹ Truly effective public consultation does not come cheap and the HGC's budget gives it little hope of generating better awareness of human genetics and addressing the public's concerns. **The Prime Minister said recently that he wishes to avoid a "retreat into a culture of unreason".³⁰ A good place to start would be to ensure that the Human Genetics Commission has access to sufficient funds to enable it to conduct an extensive and genuine dialogue with the public.**

²³ *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review*, Cabinet Office, Office of Science and Technology, May 1999

²⁴ See www.hgc.gov.uk

²⁵ Fifth Report of the Science and Technology Committee, Session 2000-01, *Genetics and Insurance*, HC 174, Appendix 26

²⁶ *Ibid*, para 74

²⁷ *Government Response to the Report from the House of Commons Science and Technology Committee: Genetics and Insurance*, Cm 5286, para 48

²⁸ Q59

²⁹ Q50

³⁰ Speech made by the Prime Minister at the Royal Society on 23 May 2002

Advisory and regulatory framework

12. The foundation of the HGC had been recommended by our predecessor Committee in 1995 but our predecessors were disappointed that initially only an advisory committee, the HGAC, was set up. The Committee's recommendation in 1995 had been that the HFEA provided a good model for a Commission, with statutory regulatory powers combined with an advisory role and a research budget.³¹ In its 2001 Report on the Scientific Advisory System, our predecessor Committee welcomed the establishment of the HGC but regretted that it had not been given statutory powers and expressed concern that "The status accorded different advisory bodies at present appears haphazard".³²

13. Although the HGC replaced three advisory committees, it still leaves other advisory and regulatory bodies active in medical genetics: the Gene Therapy Advisory Committee and the Genetics and Insurance Committee. It could be argued that these should have been incorporated into the HGC in the first place. The plethora of advisory and regulatory bodies was a concern of the Committee in the last Parliament: "a lot of committees have grown up over the years, and ... they are not in any rational pattern".³³ In its recent report *Inside Information*, the HGC suggests that the division of responsibilities with the Genetics and Insurance Committee has not worked well.³⁴ **We recommend that the Government conduct a thorough review of advice and regulation across the fields of medical genetics, embryology and reproductive medicine, with a view to producing a more streamlined structure.**

Stem cells

14. Stem cells provide the potential to treat a wide range of diseases by virtue of their ability to differentiate and develop into a range of cell types. A technique called cell nuclear replacement (CNR), which was used to create Dolly the Sheep, offers the prospect of increasing our understanding of cellular processes and of creating stem cells with a particular genetic make-up, which may be of therapeutic value. Under the Human Fertilisation and Embryology Act 1990, as enacted, research on embryos for therapeutic purposes could not be licensed by the HFEA. In November 2000, following the recommendations of a report by the Chief Medical Officer (the Donaldson Report)³⁵, the Government laid draft Regulations before Parliament, allowing the HFEA to license research involving embryos for the purposes of (a) increasing knowledge about development of embryos, (b) increasing knowledge about serious disease and (c) enabling any such knowledge to be applied in developing treatment for serious disease. The draft Regulations were passed by both Houses and came into effect on 31 January 2001 as the Human Fertilisation and Embryology (Research Purposes) Regulations 2001.

15. The ProLife Alliance sought a judicial review of the 2001 Regulations, claiming that "human embryos created by cell nuclear replacement, which process does not involve 'fertilisation', do not satisfy the definition of 'embryo' in section 1 of the 1990 Act".³⁶ On 15 November 2001 the High Court granted a declaration in the terms sought, in effect

³¹ Third Report of the Science and Technology Committee, Session 1994-95, *Human Genetics: The Science and its Consequences*, HC41-I, paras 285-286

³² Fourth Report of the Science and Technology Committee, Session 2000-2001, *The Scientific Advisory System*, HC 257, para 30

³³ *Ibid*, para 77

³⁴ *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, a report by the Human Genetics Commission, May 2002

³⁵ *Stem Cell Research: Medical Progress with Responsibility*, Report of the Chief Medical Office's Expert Advisory Group on Therapeutic Cloning, Department of Health, August 2000

³⁶ R(Quintavalle) v Secretary of State for Health

removing embryos created by CNR from regulation by the HFEA. In response, and to ensure that CNR was not used for human reproductive cloning, the Government introduced the Human Reproductive Cloning Bill on 21 November, which became law on 4 December 2001. It provides that “A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offence”. At the same time the Government appealed against the High Court’s judgment. On 18 January 2002 the Court of Appeal allowed the appeal, in effect bringing embryos created through the use of CNR within the scope of the 1990 Act. The ProLife Alliance has been given leave to appeal against this ruling to the House of Lords and a hearing is expected before the end of 2002.

16. During the debate on the Regulations on 22 January 2001, some members of the House of Lords were concerned about the speed with which legislation was being introduced and that the creation of cloned embryos could lead to human cloning (CNR could result in a cloned human if the resulting embryo were implanted in the womb). This was met by an amendment calling on the Government to support the appointment of a House of Lords Select Committee to report on the issues connected with human cloning and stem cell research, and to undertake to review the Regulations following the report of that Committee. The House of Lords Stem Cell Research Committee’s report, published on 27 February 2002, affirmed the importance of this area of research and concluded that the current regulatory framework provided sufficient protection against the development of CNR leading to human reproductive cloning.³⁷ On 28 February 2002 the HFEA approved two applications for research on human embryos to produce stem cell lines, neither of which involves CNR.³⁸ The Government published its response to the Lords Committee on 4 July 2002.³⁹

17. Embryonic stem cells are not considered to be embryos and do not fall within the remit of the HFEA.⁴⁰ Neither does the HFEA have jurisdiction over clinical trials involving adult stem cells. The Lords Committee suggested either that a new advisory committee be set up to regulate clinical studies on all types of stem cells or that the remit of the Gene Therapy Advisory Committee be extended.⁴¹ The question arises, however, why not simply extend the remit of the HFEA to cover stem cell lines? The Lords Committee took the line that research on established stem cell lines did not require the level of regulation to which human embryo research is currently subject by the HFEA. This is true, but the HFEA could readily operate a ‘lighter touch’ regulatory regime for stem cell research. We note that Ms Leather showed no enthusiasm for the HFEA taking on this role⁴² but in our view there would be benefit in avoiding the creation of yet another body in this already overcrowded regulatory field. The Government, in its response to the Lords Stem Cell Committee, says it will consider whether “further oversight of ... clinical trials involving embryonic stem cells is desirable” but highlights important differences between stem cell therapy and gene therapy.⁴³

18. The Lords Committee endorsed the Department of Health’s request to the Medical Research Council to establish a stem cell bank.⁴⁴ The MRC has set up a National Stem Cell Bank Advisory Committee which will choose an independent national laboratory as the location and oversee the bank once it has been established. Both Baroness Kennedy and Dame Ruth felt that the body that regulates clinical trials involving stem cells could include a cell bank within its remit.

³⁷ House of Lords Stem Cell Research Committee, Session 2001-2002, HL 83(i), para 5.24

³⁸ From the Centre for Genome Research in Edinburgh and from Guy’s Hospital in London.

³⁹ Government Response to the House of Lords Select Committee Report on Stem Cell Research, July 2002, Cm 5561

⁴⁰ HL 83(i), para 8.22

⁴¹ *Ibid*, para 8.23

⁴² Qq 32-43

⁴³ Cm 5561, pp 16-17

⁴⁴ HL 83(i), para 8.29

19. We recognise that different areas of expertise are needed to assess different areas of clinical research, but **the Government should operate from the principle that no more advisory and regulatory bodies should be created than are absolutely necessary and it is better to reinforce the success of existing bodies by extending their remit than to spawn ever more small specialised bodies.**

International perspectives

20. Modern medical science is a global activity. The negotiations for the European Commission's Framework Programme 6, in which some countries wished to limit the funding available for research on stem cells, demonstrate that countries with different cultural and religious backgrounds can take very different ethical stances.⁴⁵ In October 2001, the European Parliament's Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine visited Westminster.⁴⁶ It was clear from the discussion that there was considerable tension on the stem cell issue. The Council of Europe's Convention of Human Rights and Biomedicine was published in 1998. In permitting CNR, the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 are in conflict with Article 18 of the Convention, which prohibits the creation of cloned embryos for research. There is provision for a State to sign the Convention with a reservation where it is in conflict with existing legislation (Article 36), however. The UK is not a signatory to the Convention and we believe the Government should consider whether it should join as part of an international effort to prohibit human cloning. We note that the Government is supporting a draft UN convention to outlaw human reproductive cloning.⁴⁷ **We believe that the Government should remain active on the international stage, as well as domestically, in ensuring that scientific advances are facilitated yet appropriately balanced by regulatory and legislative control.**

Legislative framework

21. It is now 12 years since the Human Fertilisation and Embryology Act was enacted, and the science that informed it has been superseded. As Dame Anne McLaren says, "the HFEA seems to have a wider sphere of responsibility with every year that passes", presenting new challenges to the organisation.⁴⁸ Some of these issues create unease in some quarters. We asked the witnesses whether it was time to review the 1990 Act. Dame Ruth said that the Act might need to be amended to take account of human rights legislation and that there was too much emphasis on confidentiality in the Act (she told us that this made it difficult for the HFEA to get its computers repaired, for example).⁴⁹

22. Baroness Kennedy also suggested an area where legislation was necessary. She believed that theft of DNA should become a criminal offence and that a new body should be set up to regulate DNA databases.⁵⁰ Already there are signs that inappropriate use of DNA is taking place and the BioBank initiative, the funding of which was announced on 29 April 2002,⁵¹ has also raised concerns.⁵² The HGC's recent report *Inside Information*

⁴⁵ Q46

⁴⁶ The Committee met with members of our predecessor Committee (including members of the current Committee) and the House of Lords Science and Technology Committee.

⁴⁷ Cm 5561, pp 13

⁴⁸ Ev 12

⁴⁹ Q31

⁵⁰ Q62

⁵¹ Joint news release issued by the Wellcome Trust, the Medical Research Council and the Department of Health

⁵² HC Deb, 3 July 2002, cols 365-372

discusses this and many other issues surrounding the use of personal genetic data.⁵³ We are aware that some see a need for much stronger legislation in this area to protect genetic privacy, to prevent genetic discrimination and to regulate the commercial exploitation of genetic samples.⁵⁴

23. Some witnesses told the Lords Stem Cell Research Committee that they believed the 2001 Regulations to be ultra vires the Human Fertilisation and Embryology Act in extending the Act to cover basic research. While the Stem Cell Committee did not believe this to be the case, it suggested new legislation to make “express provision for such basic research as is necessary as a precursor for the development of cell-based therapies”.⁵⁵ In its response to the Stem Cell Committee, the Government said it had “no reason to believe that legislation will be required for the foreseeable future”.⁵⁶ The Committee identified where scientific advances might require new legislation: the mixing of animal eggs with human cells; the dedifferentiation of adult stem cells to form the equivalent of a zygote (a fertilised egg) which could go on to form an embryo; the generation of an embryo from an oocyte (egg); the induction of differentiation using animal material; and the induction of embryonic stem cells into an embryo.⁵⁷ **The House of Lords Stem Cell Research Committee has identified several areas which might require new legislation. The Government should work on the premise that these developments will happen sooner rather than later and introduce legislation accordingly.**

24. The ProLife Alliance is appealing to the House of Lords over the High Court’s decision that embryos formed by CNR are covered by the HFE Act. This would leave any embryo formed by means other than by fertilisation completely unregulated, although the Human Reproductive Cloning Act has made illegal the implantation of such an embryo in the womb. The Government remains “satisfied that any embryo research that used CNR is covered by the 1990 Act”.⁵⁸ **Should the ProLife Alliance’s appeal to the House of Lords be successful, we urge the Government to introduce new legislation to bring the creation of embryos by whatever means within the remit of the 1990 Human Fertilisation and Embryology Act.**

25. On 13 December 2001, the HFEA decided to allow tissue typing in conjunction with preimplantation genetic diagnosis (PGD) for serious genetic diseases. This decision led to a clinic being awarded a licence from the HFEA to implant an embryo with a genetic profile that would enable the baby to donate bone marrow to an older sibling with beta thalassaemia. Questioned on the decision, Dame Ruth asserted that “The public has been consulted about preimplantation genetic diagnosis”.⁵⁹ The consultation of which she spoke was begun in November 1999 by the HFEA and the former Advisory Committee on Genetic Testing. Yet this did not address the issue of tissue typing to benefit an existing family member. Indeed, the HFEA/HGC Joint Working Party set up in December 2000 to consider the results of the consultation specifically ruled out such a procedure, stating in its report that “there were sufficient ethical difficulties with this approach that it should be subject to further discussion”.⁶⁰ Further discussion did indeed take place before a decision was made, but only within the HFEA’s own ethics committee.⁶¹ **The HFEA’s decision to allow tissue typing in conjunction with preimplantation genetic diagnosis went**

⁵³ *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, a report by the Human Genetics Commission, May 2002

⁵⁴ Response to HGC consultation on personal genetic information from Human Genetics Alert, see ww.hgalert.org

⁵⁵ HL 83(i), para 8.10-8.15

⁵⁶ Cm 5561, pp 16

⁵⁷ HL 83(i), paras 8.18-8.19

⁵⁸ Cm 5561, pp 6

⁵⁹ Q7

⁶⁰ *Outcome of the Public Consultation on Preimplantation Genetic Diagnosis*, HGC/HFEA, November 2001, paragraph 29

⁶¹ *Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors*, Ethics Committee of the HFEA, November 2001

beyond the scope of its own public consultation. It is vital that the public are taken along with decisions of such ethical importance.

26. We take issue with Dame Ruth's assertion that the fact that the HFEA took the decision on PGD "protects Members of Parliament from direct involvement in that sort of thing".⁶² Parliament does not need protecting and democracy is not served by unelected quangos taking decisions on behalf of Parliament. A pressure group, Comment on Reproductive Ethics, is seeking judicial review in the High Court on PGD on the grounds that the 1990 Act only permits distinguishing between embryos on the basis of whether they are healthy or not or for providing treatment services to the mother. Should this ultimately be successful, Parliament's intervention may be inevitable.

27. The Government has recently been conducting a consultation on the question of introducing new Regulations under the HFE Act to enable the offspring resulting from donated sperm, eggs or embryos to learn the identity of the donor. The issue was considered in Parliament during the passage of the Act but this may be another area that needs an overhaul.

28. Dame Ruth felt that new legislation on human embryology risked becoming "enmeshed with opponents of abortion".⁶³ This may be true but we cannot accept that Parliament should not be asked to consider major ethical issues for fear that elected representatives might come to a view that is different from that of the scientific community. The debates that took place on the Human Fertilisation and Embryology (Research Purposes) Regulations in December 2000 (Commons) and January 2001 (Lords), and on the Human Reproductive Cloning Bill in December 2001 showed that Parliament is well capable of considering these sensitive subjects sensibly. **The Government's apparent reluctance to enact new legislation in this sensitive area has led to a position where the 1990 Act is open to legal challenge. We recommend urgent action to remedy this and reconnect the Act with modern science.**

⁶² Q5

⁶³ Q33

LIST OF RECOMMENDATIONS AND CONCLUSIONS

1. **We welcome the intended breadth of the forthcoming Green Paper on Genetics and hope it embraces the views we express in this Report (paragraph 3).**
2. **The HFEA is asking for its income to be more than doubled. We accept that its activities have increased in recent years but, for such a large increase, it needs to make a more detailed financial case than its consultation document provides. If it can prove the need for such a large increase, it should be met by increased contributions from Government as well as from licensees. We are concerned that the Government's insistence that any increase in funding should be met from licence fees alone undermines the principle that the HFEA should have no incentive to award licences (paragraph 6).**
3. **Britain is well placed to be a world leader in human genetics and embryology research and it is crucial that our scientists, in complying with regulatory requirements, are not hampered by bureaucracy (paragraph 7).**
4. **The HFEA's new emphasis on communication with the public is welcome. Continued public confidence demands that the HFEA takes the lead in encouraging awareness and debate about research and treatment involving human embryos (paragraph 8).**
5. **The Prime Minister said recently that he wishes to avoid a "retreat into a culture of unreason". A good place to start would be to ensure that the Human Genetics Commission has access to sufficient funds to enable it to conduct an extensive and genuine dialogue with the public (paragraph 11).**
6. **We recommend that the Government conduct a thorough review of advice and regulation across the fields of medical genetics, embryology and reproductive medicine, with a view to producing a more streamlined structure (paragraph 13).**
7. **The Government should operate from the principle that no more advisory and regulatory bodies should be created than are absolutely necessary and it is better to reinforce the success of existing bodies by extending their remit than to spawn ever more small specialised bodies (paragraph 19).**
8. **We believe that the Government should remain active on the international stage, as well as domestically, in ensuring that scientific advances are facilitated yet appropriately balanced by regulatory and legislative control (paragraph 20).**
9. **The House of Lords Stem Cell Research Committee has identified several areas which might require new legislation. The Government should work on the premise that these developments will happen sooner rather than later and introduce legislation accordingly (paragraph 23).**
10. **Should the ProLife Alliance's appeal to the House of Lords be successful, we urge the Government to introduce new legislation to bring the creation of embryos by whatever means within the remit of the 1990 Human Fertilisation and Embryology Act (paragraph 24).**

- 11. The HFEA's decision to allow tissue typing in conjunction with preimplantation genetic diagnosis went beyond the scope of its own public consultation. It is vital that the public are taken along with decisions of such ethical importance (paragraph 25).**
- 12. The Government's apparent reluctance to enact new legislation in this sensitive area has led to a position where the 1990 Act is open to legal challenge. We recommend urgent action to remedy this and reconnect the Act with modern science (paragraph 28).**

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

WEDNESDAY 10 JULY 2002

Members present:

Dr Ian Gibson, in the Chair

Mr Tom Harris
Mr David Heath
Mr Mark Hoban
Dr Brian Iddon

Mr Tony McWalter
Geraldine Smith
Bob Spink
Dr Desmond Turner

The Committee deliberated.

Mr Heath and Bob Spink declared an overseas visit to Germany from 19-21 March 2002 as a guest of the German Ambassador to discuss the ethical, moral and social issues surrounding emerging science.

Draft Report (Developments in Human Genetics and Embryology), proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 28 read and agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No. 134 (Select committees (reports)) be applied to the Report.

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.—(*The Chairman.*)

[Adjourned till Monday 15 July at Four o'clock.]

LIST OF WITNESSES

Wednesday 24 April 2002

Ruth Deech, former Chair, Human Fertilisation and Embryology Authority, Baroness Kennedy of the Shaws, Chair, Human Genetics Commission, and Suzi Leather, Chair, Human Fertilisation and Embryology Authority Ev 1

LIST OF APPENDICES TO THE MINUTES OF EVIDENCE

1. Memorandum submitted by Professor Robin Lovell-Badge, National Institute for Medical Research Ev 11
2. Memorandum submitted by Dame Anne McLaren, Wellcome Trust/Cancer Research UK Institute of Cancer and Developmental Biology Ev 12
3. Memorandum submitted by Suzi Leather, Chair, Human Fertilisation and Embryology Authority Ev 12
4. Memorandum submitted by Professor Austin Smith, Centre for Genome Research, University of Edinburgh Ev 14