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DEPARTMENT OF HEALTH

GOVERNMENT RESPONSE TO THE REPORT FROM THE HOUSE OF COMMONS SCIENCE AND TECHNOLOGY COMMITTEE: DEVELOPMENTS IN HUMAN GENETICS AND EMBRYOLOGY

Presented to Parliament by the Secretary of State for Health
By Command of Her Majesty
November 2002

Cm 5693

£4.50

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FOREWORD

On 18 July 2002 the House of Commons Science and Technology Committee published a report on '*Developments in Human Genetics and Embryology*'. Although short, the report highlights several important issues.

The Government recognises that this Committee and its predecessors have taken a long-standing interest in human genetics research and its applications. This report builds on a number of significant earlier reports including the 1995 report on '*Human Genetics: the Science and its Consequences*' and the 2001 reports on '*Genetics and Insurance*' and '*The Scientific Advisory System*'.

We welcome the Committee's contribution to the debate on these important issues and its intention to continue to monitor developments in this area.

RESPONSE TO THE COMMITTEE'S RECOMMENDATIONS AND CONCLUSIONS

Recommendation 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).

1. The forthcoming Green Paper on genetics will cover the impact of genetics on human health and healthcare. The main focus will be on preparing the NHS to maximise the benefits of genetic advances in improving patient care. It will also cover ethical and social issues raised by genetic research and genetic technologies, as well as clinical and scientific issues. We will certainly take the Committee's views into account in developing the Green Paper.

Recommendation 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).

2. The Government believes it is essential that the HFEA should be a strong and effective regulator of clinics providing fertility treatment and carrying out research using human embryos. We accept that the HFEA's activities have increased in recent years and that it needs an increase in resources. We also agree that the HFEA needs to make a satisfactory case to justify an increase in funding.

3. It is Government policy that services that are regulated should bear the cost of regulation. It is in the interests of clinics providing *in vitro* fertilisation that their industry is effectively regulated. This prevents unscrupulous operators from undercutting the market by offering a sub-standard service and ensures that public confidence in fertility treatment is maintained and patient safety assured. Since the clinics benefit from regulation we believe it is appropriate they should meet the costs. We do not agree that this principle means that the HFEA has an incentive to award licenses, since the fees set should only cover the actual costs of the work involved. This is made clear in '*The fees and charges guide*' published by the Treasury which states "the fee for a statutory service should never be set deliberately to create a surplus".

4. Following their public consultation exercise in summer 2002 the HFEA has proposed an increase in the fees that clinics pay per treatment cycle, to £100 for IVF and £50 for donor insemination (from £40 and £20 respectively) to come into force from 1 January 2003. The fees have

remained largely the same since the HFEA was established in 1991. The Government therefore believes that the proposed increases are reasonable and has accepted them. However, we do not think it is reasonable that they should take effect from 1 January 2003 as this would not give the clinics time to prepare for them. We have therefore agreed to bear the cost of putting back the introduction of the increase until 1 April 2003.

5. The Government contributes to the HFEA's funding to cover the cost of the work the Authority carries out which is unrelated to the service it provides to clinics and research institutions. The Government's contribution is currently set at £0.6 million. However, this baseline funding is under review and we have agreed to increase it to £1.5 million for 2003-04 pending the outcome of that review.

6. In addition, in recent years, the Government has looked sympathetically at bids for additional in-year funding from the Authority for specific work. Examples are to meet the costs of external legal and professional advice, to upgrade the Authority's facilities and to cover the cost of additional policy work such as the consultation exercise the Authority is currently carrying out on sex selection. An additional £1 million funding was provided in 2001-02 and a further £1.1 million has been allocated in 2002-03.

7. The Government also recognises that major capital investment is needed by the HFEA to upgrade its information management systems. The Government has agreed to bear the cost of this, subject to receipt of a satisfactory full business case. £1.5 million has already been allocated in 2002-03 for initial work.

Recommendation 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).

8. We agree with the Committee that the UK is well placed to be a world leader in research in these fields. We fully concur with the Committee that scientists should not be hampered by unnecessary bureaucracy and that the HFEA should process research applications efficiently. At the same time however it is essential that applications are considered carefully and thoroughly. Indeed, the UK's position as a world leader is enhanced by the robust nature of its regulatory process.

9. The HFEA aims to process an application for research using human embryos within three months of receipt of a complete application. Each application is overseen by a regulatory manager at the HFEA who remains the first point of contact for the applicant throughout the process. Centres that do not already hold a research licence are inspected and a report produced assessing their suitability. Applications are also peer reviewed before a licence committee considers each one on its merits. If an application is refused then the applicant may appeal against that decision. We acknowledge that the HFEA has not always met its targets for dealing with research applications. We will continue to monitor HFEA's performance in this area and ask them to ensure they make improvements to their systems.

Recommendation 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).

10. We agree that the public has a keen interest in the work and administration of the HFEA and that the Authority has a responsibility to communicate effectively with the public. This is important to enable the public to have input to the development of policies and to help ensure that patients undergoing assisted conception treatment are aware of what the treatment entails and any associated risks.

11. To date the HFEA has completed 11 formal public consultations and they published their latest consultation document '*Sex Selection: Choice and Responsibility in Human Reproduction*' in October. The HFEA also provides information to the general public through its website, its printed publications and by responding to written and telephone enquiries. The Authority is particularly keen to hear the views of patient organisations and involved them fully in the series of meetings it held with its stakeholders during the summer to discuss its proposals for fee increases. The new Chair of the Authority, Suzi Leather, has made clear that she is committed to improving the HFEA's communications strategy and, like the Committee, we welcome this.

Recommendation 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).

12. The Human Genetics Commission is specifically tasked with consulting the public and encouraging debate on human genetic technologies and their actual and potential applications. The Government considers that the HGC has been highly effective in fulfilling this remit. From the start the Commission has held its meetings in public, made its papers available and sought new methods of consulting the public. It commissioned a survey of people's attitudes towards the uses of personal genetic information which formed the background to its major consultation on this subject. The consultation '*Whose hands on your genes*' was launched at a large public meeting in Newcastle. This included students from local schools as well as a wide range of local people. The HGC has also set up a Consultative Panel of over 100 people affected by a genetic condition. This will provide an invaluable sounding board when preparing consultations and reports. Most recently the HGC has issued a consultation document on the supply of genetic tests direct to the public.

13. The Government has already given a commitment to keep HGC's resources under review. We are not aware that this budget is inadequate for the work that the Commission currently has planned. In some cases the HGC has received additional funding for specific pieces of work, such as funding from the Department of Health's Public Health Development Fund for its survey of public attitudes to human genetics. We will consider

sympathetically any future proposals from the HGC to fund specific pieces of work in order to undertake their public engagement work effectively.

Recommendation 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).

14. As the Committee recognises, the Government published a major review of the regulatory and advisory framework for biotechnology in 1999[1]. As part of streamlining the advisory framework following this review the Human Genetics Commission was established in May 1999 to act as a strategic advisory body on human genetics. Three existing advisory committees (the Advisory Committee on Genetic Testing, the Advisory Group on Scientific Advances in Genetics, and the Human Genetics Advisory Commission) were wound up and their responsibilities passed to the HGC.

15. However, the review was clear that the HGC should **not** be involved in "the case by case examination of individual applications for new products or processes" and that this should continue to be the responsibility of specialist regulatory/technical committees. The review concluded that the three existing regulatory bodies in the field of human genetics (described below) should continue and that, if necessary, the Government should direct the HGC not to take on work which could be better carried out by another committee.

16. The Gene Therapy Advisory Committee (GTAC) is responsible for assessing the ethical acceptability of individual proposals for clinical gene therapy research, taking account of the medical and scientific merits and the potential benefits and risks, and provides advice to UK Health Ministers on developments in gene therapy research. GTAC's primary concern is patient welfare. Members of GTAC include those with specialist expertise in gene therapy, virology, immunology, haematology, molecular biology, oncology, surgery and clinical genetics, as well as one-third lay members (including members from patient support groups) and one member with experience from the pharmaceutical industry.

17. The Genetics and Insurance Committee (GAIC) provides independent scrutiny of compliance with the Association of British Insurers Code of Practice and the terms of the 5-year moratorium agreed in 2001 on the use of genetic test results by insurance companies. The Committee is responsible for making decisions about whether insurers should be allowed to use the results of particular genetic tests in setting premiums for high value insurance policies above the limits of the moratorium. It also provides advice to Government on issues around genetics and insurance.

1 *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review* published in May 1999 by the Cabinet Office and the Office of Science and Technology

In addition to insurance and genetics experts, including actuaries and underwriters, GAIC has members from patient support groups, genetic counselling and with expertise in consumer affairs.

18. The Human Fertilisation and Embryology Authority (HFEA) is the statutory body which licenses and regulates centres in the UK that carry out *in vitro* fertilisation, donor insemination, the storage of gametes (sperm or eggs) or embryos and human embryo research. The HFEA's functions are clearly set out in the Human Fertilisation and Embryology Act 1990.

19. We believe that the HGC and the three regulatory/technical bodies described above have distinct and different remits which dovetail effectively and we believe that the conclusions of the 1999 review remain valid. Each body has regard to the others' work and they maintain close links. However, the HGC is expected to keep the position under review and to advise Ministers on whether there are inappropriate overlaps or gaps between the different bodies in this rapidly developing field.

Recommendation 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).

20. The Government agrees with the Committee that advisory and regulatory bodies should only be established where absolutely necessary and we would always want to consider as a first option extending the remit of an existing body where possible.

21. The Committee highlights the issue of stem cells in this regard. As the Committee rightly comments, stem cells provide the potential to treat a wide range of diseases by virtue of their ability to differentiate and develop into a wide range of cell types. For this reason the 2000 report of the Chief Medical Officer's expert group *Stem Cell Research: Medical Progress with Responsibility* recommended the expansion of the permitted purposes of embryo research under the Human Fertilisation and Embryology Act 1990 to allow research to increase understanding about human disease and disorders and their cell-based treatments. It also recommended that the Research Councils should consider the feasibility of establishing collections of stem cell lines for research use.

22. Since then the Medical Research Council (MRC) has worked with the Department of Health and regulatory bodies to establish a national stem cell bank which will begin to access cell lines during 2003. This bank will hold all forms of stem cell lines, whether derived from embryonic, fetal or adult tissue. The MRC has established the National Stem Cell Bank Advisory Committee, which will oversee the operation of the stem cell bank and control access to the bank by researchers. This is an MRC committee and not a Government body. It includes scientists, ethicists and consumer representatives and will have observers from each of the relevant regulatory agencies and the Department of Health.

23. The Committee suggests that the HFEA's remit could be broadened to encompass both the oversight of the stem cell bank and the regulation of research on stem cell lines. However, we do not think this would be appropriate since the role of the Authority as set out in the Human Fertilisation and Embryology Act 1990 is to license certain types of infertility treatment and research using human embryos. As the Committee recognises, embryonic stem cell lines are not considered to be embryos and therefore do not fall within the HFEA's remit. Moreover, it would be entirely outside the scope of the HFEA to regulate the use of fetal or adult stem cells. For it to do so would be a very major change in its role and given the established use of both cord blood and adult stem cells in treatment of cancer, it would mean a major shift in the direction of its work. Primary legislation would clearly be required to extend the remit of the HFEA in this way. The Government does not believe this is either necessary or desirable. The stem cell bank is already being set up and the Government is satisfied with the MRC's oversight arrangements, as set out above.

24. With regard to the regulation of clinical trials using stem cells, the House of Lords Select Committee on Stem Cells suggested that the role of the Gene Therapy Advisory Committee could be extended to cover this. As we said in response to that report, the oversight of clinical trials using stem cells is something we will keep under review. Current scientific evidence suggests that it may be several years before embryonic stem cell research can be translated into products for clinical trials. A great deal of basic research will be necessary before this stage is reached and it is this crucial research that we hope the establishment of the stem cell bank will facilitate. We therefore believe that it would be premature at this stage either to set up a body to monitor clinical trials or to extend the remit of an existing body. However we will keep the need for further oversight in the future under consideration.

Recommendation 8

We believe 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).

25. The UK Government remains active in a multitude of international initiatives that cover genetics and related scientific advances. We continue to work within the settings of the Organisation for Economic Co-operation and Development (OECD), European Union, Council of Europe, UNESCO, United Nations and other international fora. The UK was actively involved in the recent work of OECD on standards and quality control of genetic testing and we continue to participate in the work of the Council of Europe to develop a protocol to the Convention on Human Rights and Biomedicine concerning genetics.

26. The Government supports the aim of an international ban on human reproductive cloning whilst not preventing therapeutic cloning, subject to proper robust regulation. We are one of the few countries in the world to have specifically banned human reproductive cloning in the Human Reproductive Cloning Act 2001. We have played an active role in the discussions within the United Nations concerning a possible UN Convention to ban reproductive cloning and we will continue to do so.

27. The Council of Europe's Convention on Human Rights and Biomedicine contains a wide range of complex ethical and legal issues, many of which have been under active debate in the UK over recent years. The Government wishes to consider the conclusions of those debates before reaching a decision on signature or ratification of the Convention. Most recently, we have consulted on the provisions of the Convention concerning transplantation in '*Human Bodies, Human Choices: The Law on Human Organs and Tissue in England and Wales*'. That consultation closed on 14 October 2002, and we are presently considering the responses received.

Recommendation 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).

28. Although the House of Lords Select Committee on Stem Cell Research considered whether scientific advances required new legislation they concluded that the existing regulatory platform was sufficient in almost all regards. In respect to the scope of the Human Fertilisation and Embryology Act 1990 and the Human Fertilisation and Embryology (Research Purposes) Regulations 2001, the House of Lords Committee made just one specific recommendation (in para 8.15) that the Government "consider making express provision for basic research...as a precursor for the development of cell based therapies".

29. The Government response to the House of Lords Select Committee issued in July 2002 states that we agree with the House of Lords Committee that basic research as well as applied research should be allowed under the regulations and that we are confident that the existing regulations do cover this type of research. We have no reason to believe that further legislation will be required for the foreseeable future, but we undertook to keep this aspect under review. That remains our position.

Recommendation 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).

30. If the ProLife Alliance's appeal is successful, the result would be that embryos created by cell nuclear replacement would not be subject to regulation. This is unacceptable to Government. Our view is that all embryos, however created, deserve the same protection and that they are subject to the controls and safeguards of the 1990 Act and the 2001 Research Purposes Regulations. We have already stated our intention to introduce new legislation to cover therapeutic cloning should the ProLife Alliance's appeal succeed. We agree with the Committee that it would be essential to ensure that such legislation covered embryos created by any means.

Recommendation 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).

31. It is correct that the public consultation on preimplantation genetic diagnosis (PGD) begun in 1999 and undertaken jointly by the then Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority did not specifically address the extension of PGD to include tissue-typing.

32. However, as the Committee itself recognises elsewhere in its report, it is essential that the HFEA should process applications in a timely and efficient manner. In this case, the HFEA received an application in 2001 to use this particular technique in an attempt to benefit an existing sibling suffering from a serious genetic disorder. The Authority concluded that it had a duty to deal with the application and that it would not be appropriate to carry out a further public consultation before making its decision. However both the ethics committee and the full Authority considered the issues involved in great depth. They concluded that the technique could be used where the embryos were themselves at risk of inheriting a serious genetic disease and provided each case was considered individually.

33. The Government believes it is essential that the HFEA should take account of public opinion in reaching its decisions. However we do not believe that this should necessarily involve a formal public consultation in each case. We also agree with the Committee that it is vital that the HFEA communicates its decisions and the reasons behind them clearly so that, so far as possible, the public understands the basis for decisions of ethical importance.

Recommendation 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).

34. The 1990 Act is now over 10 years old. Understanding and technology in the field of reproductive medicine has moved on during this time, but we believe the 1990 Act is functioning reasonably well and provides a framework within which new advances can be appropriately accommodated. However, we are committed to keeping the position under review and will continue to monitor scientific developments in the field of assisted reproduction to ensure the legislation covers them effectively. We will also of course want to take account of any successful legal challenges to the Act and we will seek appropriate legislative means to make any changes which may become necessary.

35. The Government is not reluctant to enact new legislation in this sensitive area. As the Committee recognised, when the High Court found in favour of the ProLife Alliance last year and ruled that the 1990 Act did not cover embryos created by cloning we took immediate steps to introduce new legislation to ban human reproductive cloning - without waiting for the outcome of the appeal. In the event, the Court of Appeal found in our favour, although as stated above we are committed to amending the 1990 Act to cover embryos irrespective of their means of creation should the ProLife Alliance's appeal to the House of Lords succeed.

36. The Committee also expressed the view that the legislation dealing with the provision of information to people born as a result of sperm, egg or embryo donation may need overhauling. From December 2001 until July 2002 we conducted a public consultation on this subject. This included the possibility of making regulations under section 31 of the 1990 Act to specify the categories of non-identifying information that may be provided to donor-conceived people at age 18 and identifying information about future donors. We have made it absolutely clear that we do not intend to permit the retrospective identification of existing donors and believe that the existing regulation making powers provide sufficient flexibility to introduce any changes that may be agreed. We are in the process of analysing the responses to the consultation and will announce our view on the need for regulations once this is completed.

37. We agree with the Committee that Parliament has debated issues of great complexity and ethical importance in depth and with considerable sensitivity, as exemplified by the excellent debates on the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 and the Human Reproductive Cloning Act 2001. Parliament will continue to be asked to consider major ethical issues and we would anticipate that future debates will be of an equally high standard.

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