Cloning issues in reproduction, science and medicine : government response to the report by the Human Genetics Advisory Commission and the Human Fertilisation and Embryology Authority on cloning issues in reproduction, science and medicine / presented to Parliament by the Secretary of State for Health by command of Her Majesty, June 1999.

DEPARTMENT OF HEALTH

DEPARTMENT OF TRADE AND INDUSTRY

OFFICE OF SCIENCE AND TECHNOLOGY

CLONING ISSUES IN REPRODUCTION, SCIENCE AND MEDICINE

GOVERNMENT RESPONSE TO THE REPORT BY THE HUMAN GENETICS ADVISORY COMMISSION AND THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY ON CLONING ISSUES IN REPRODUCTION, SCIENCE AND MEDICINE

Presented to Parliament by the Secretary of State for Health
by Command of Her Majesty
June 1999

LONDON: TSO
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Foreword

In February 1997 ***Nature***[1] published an account of research by the Roslin Institute and PPL Therapeutics Plc leading to the birth of a cloned[2] sheep, called 'Dolly'. Dolly was not the first cloned sheep, there were 'Morag' and 'Megan' before her, but what made her unique was that she was cloned using a cell taken from an adult sheep rather than using an embryonic or fetal cell. This remarkable breakthrough reawakened public interest, and concern, about the implications for humans of cloning research.

On the day of the publication in ***Nature***, the House of Commons Science and Technology Committee decided to conduct an inquiry into this issue. The Committee's Report ***The Cloning of Animals from Adult Cells***[3] considered among other things the extent to which the existing legislative framework regulated cloning using the approach pioneered at Roslin. Recommendations included the possibility of primary legislation to ensure that such cloning came within the scope of the Human Fertilisation and Embryology Act 1990, and sought confirmation from the Government that human cloning should be banned.

The Government position was made absolutely clear in the response by the Minister for Public Health to a Question in Parliament on 26 June 1997 when she said:

"We regard the deliberate cloning of human beings as ethically unacceptable. Under United Kingdom law, cloning of individual humans cannot take place whatever the origin of the material and whatever technique is used."

This remains the Government's position.

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[1] *Viable Offspring Derived from Foetal and Adult Mammalian Cells* Nature, 385, 881: 1997

[2] Cloning is defined as the production of a cell or organism with the same nuclear genome as another cell or organism.

[3] *Fifth Report: HC 373-1; 18 March 1997* The Stationery Office.

We welcome the joint Human Fertilisation and Embryology Authority/Human Genetics Advisory Commission Report ***Cloning Issues in Reproduction, Science and Medicine***. We are grateful to the members of the HFEA and the HGAC, and in particular the members of the working group, for undertaking the review of this difficult and sensitive subject.

Public debate in this rapidly developing area is timely, but the issues raised and their consequences are not always clear. The consultation document published in the course of the review set out the background to these issues, and discussed them in a clear and understandable way. The thoughtful nature of many of the responses reflected the extent to which public understanding had been informed by this exercise.

Among other things, the Report confirms the Government's view that the Human Fertilisation and Embryology Act 1990 is wholly adequate to forbid human reproductive cloning in the United Kingdom.

We agree with the Report's conclusion that, for a number of reasons, there are serious ethical concerns about reproductive cloning as a means to relieve infertility, or for any other reason, and welcome the support given by the public consultation to our policy of forbidding human reproductive cloning.

We accept the Report's recommendation of the need to keep this, and related issues, under review. This is important not only to meet real public concerns about rapid developments in these areas of science and medicine, but also to ensure that the ethical debate keeps pace with scientific and medical developments.

We believe that some further consideration is needed before we can make firm decisions on some of the recommendations made in the Report. But we are grateful to the members of the HFEA and HGAC for providing a sound base for further development.

Tessa Jowell
Minister for Public Health
Department of Health

David Sainsbury
Minister for Science
Department of Trade and Industry

THE GOVERNMENT RESPONSE TO THE ISSUES RAISED IN THE JOINT REPORT OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY (HFEA) AND HUMAN GENETICS ADVISORY COMMISSION (HGAC).

UK safeguards to prevent human reproductive cloning

1. The Report recommends that the safeguards currently in place in the United Kingdom are recognised as being wholly adequate to forbid human reproductive cloning. These safeguards include the provisions of the Human Fertilisation and Embryology Act 1990 ('the 1990 Act'), and the decision by the Human Fertilisation and Embryology Authority that it will not license the use of nuclear replacement for human reproductive cloning.

2. The Government welcomes the recognition that the safeguards in place are wholly adequate to prevent human reproductive cloning in the United Kingdom. The Government reaffirms its unequivocal position that the deliberate cloning of individual humans is ethically unacceptable.

3. However, the Report goes on to suggest that the Government may wish to consider legislation explicitly banning reproductive cloning. The Report also recognises that the pace of scientific advance in human genetics is such that these issues should be kept under regular review to monitor scientific progress. It recommends that these should be re-examined in five years time, in the light of developments and public attitudes towards them.

4. Given the potential speed of developments in this area the Government, with the assistance of its advisory bodies, will keep under continuing review the adequacy of the existing safeguards and the possible need for additional legislation, with a further detailed analysis in 5 years time if necessary.

Research for therapeutic purposes

5. The Report also considered whether the current provisions in the 1990 Act were sufficient to allow research for therapeutic purposes, which involved the use of cell nuclear replacement or cloning techniques but **not** human reproductive cloning. At present, the 1990 Act permits the use of human embryos, in strictly controlled circumstances, for research into infertility, contraception and related matters. The Report recommends that consideration should be given to specifying in regulations under the 1990 Act two further purposes for the use of human embryos in research. These would permit the development of methods of therapy (i) for mitochondrial diseases and (ii) for diseased or damaged tissues or organs.

6. The Government recognises that these possible changes to the legislation should be considered. We have therefore asked the Chief Medical Officer to establish an expert advisory group to seek the views of research institutions and others, among other things to establish more clearly the evidence of potential benefits for human health of such research. The Government's Chief Scientific Advisor will be a member of this group.

7. The Government believes that this is necessary to establish the extent to which there is likely to be an identified need for and interest in such research and when such interest is likely to arise. It will also provide an opportunity to obtain details of the anticipated benefits; the potential risks; and views on the alternative approaches that might be pursued to the same end. The consultation will begin during the summer, with conclusions expected by early next year.

8. The Government notes that any proposal to make regulations under the 1990 Act to extend the purposes for which research licences may be issued would require a draft to be laid before and approved by resolution of each House before coming into force. This would ensure that Parliament had an opportunity to debate fully the issues raised, and to decide whether the proposals were acceptable.

9. The Government also notes that the 1990 Act already provides for strict controls to be placed on research involving the use of human embryos. This includes that such research may only be undertaken in accordance with a licence issued by the HFEA, which must be satisfied that any proposed use of embryos is necessary for the purposes of the research. HFEA membership includes a wide range of expertise and interests, and the Government has every confidence in the regulation and monitoring by the Authority of embryo research and related activities under the terms of the 1990 Act.

Ethical issues relating to genetic identity

10. The Government accepts the Report's conclusion that the protection of genetic identity, so far as it relates to the issues raised in the Report, does not appear to raise any new ethical issue at this time. However, this is a rapidly advancing area which the Government will continue to monitor.

Open and informed debate

11. The Government agrees with the Report's conclusion that there is a need for more education and informed debate about the new genetics and welcomes the contribution made by HGAC. The public has been involved in a number of initiatives in this and related areas, such as the review of the framework for overseeing developments in biotechnology and genetic modification, and on developments in the biosciences.

The international perspective

12. The Government supports the principles enunciated in the international agreements already reached with the aim of prohibiting human reproductive cloning. These include the Council of Europe *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*; and the UNESCO *Universal Declaration on the Human Genome and Human Rights*. The Government shares the view of HGAC and HFEA on the need for careful drafting of international instruments in this field and will consider carefully any further proposals for international initiatives on cloning.

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