Government response to the report from the House of Commons Science and Technology Committee : Government proposals for the regulation of hybrid and chimera embryos / presented to Parliament by the Secretary of State for Health by Command of Her Majesty.

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the Secretary of State for Health
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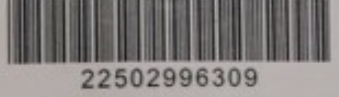

Government Response to the Report from the House of Commons Science and Technology Committee: Government proposals for the regulation of hybrid and chimera embryos

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Foreword

On 5 April 2007, the House of Commons Science and Technology Committee published a report on *Government proposals for the regulation of hybrid and chimera embryos*, following a short inquiry.[1] This followed the Government's White Paper,[2] *Review of the Human Fertilisation and Embryology Act* in December 2006, which set out policy proposals for draft legislation.

The Government welcomes the Select Committee's report on this scientifically complex and ethically contentious area of research. The evidence presented to the Committee during the inquiry complemented the responses to the Government's public consultation on this subject, allowing a broad spectrum of views to be aired.

The White Paper reflected the Government's view that it is of primary importance to clarify which hybrids and chimeras warrant regulation by the proposed Regulatory Authority for Tissue and Embryos. The White Paper also reflected the stance the Government had taken to date on the prohibition of the creation of such entities but, in recognition of the potential benefits of research, the White Paper proposed to allow scope for exemptions to be made to the prohibition.

The draft Human Tissue and Embryos Bill,[3] published on 17 May 2007 for pre-legislative scrutiny by a joint House of Commons and House of Lords Committee, largely maintains this position. However, it also acknowledges the consensus view of the Select Committee that hybrids and chimeras should be allowed to be created for research purposes. This acknowledgement is represented by the Government now proposing specifically which types of inter-species embryos (as the draft Bill refers to hybrids and chimeras) set out in the draft Bill should be allowed to be created, subject to the usual legislative requirements of the research being necessary or desirable. In the Government's view, the Select Committee report has therefore very helpfully moved this debate forward.

This paper sets out the Government's response to all of the report's 34 conclusions and recommendations. Recommendations addressing the same issue have been grouped together where appropriate.

1 Fifth report of session 2006–07, HC 272-I, oral and written evidence published as HC 272-II.
2 *Review of the Human Fertilisation and Embryology Act: Proposals for revised legislation* (including establishment of the Regulatory Authority for Tissue and Embryos).
3 Draft Human Tissue and Embryos Bill 2007.

Response to the Science and Technology Committee

Consultation process

Recommendation 1

We regret that the Department of Health did not seek to specify more clearly in its consultation what views it was seeking, nor to evaluate fully the responses of the public consultation exercise. We recommend that in future a more systematic statistical or scientific approach is developed to quantify and qualify the results of public consultation. (Paragraph 41)

Recommendation 31

We take criticisms of the Government's consultation seriously and we recommend that they be taken into consideration both in relation to the proposals for revised legislation in this area and in future consultation exercises. (Paragraph 111)

1. The Government published its consultation document on 16 August 2005 with a closing date for responses of 25 November 2005.[4] This followed the extensive report from the Science and Technology Committee, *Human Reproductive Technologies and the Law,* which addressed the issue of hybrids and chimeras.[5] The consultation received 535 responses. A report was subsequently published analysing the responses received, produced by People, Science and Policy Ltd. The report summarised the landscape of arguments put forward. We ask the Committee to note that the regulation of hybrid and chimera embryos was only one of the 74 questions and proposals broached in this wide-ranging consultation.

2. The consultation was developed in line with previous Government consultations. However, we are happy to take on board the Committee's comments when undertaking and analysing any future consultation.

4 *Review of the Human Fertilisation and Embryology Act: A Public Consultation*, Department of Health, 2005.
5 Fifth report of session 2004–05, HC 7–I, oral and written evidence published as HC 272-II.

Moral and ethical concerns

Recommendation 2

We recognise the sincere ethical and moral concerns associated with research of this nature and are therefore concerned that, to respond to these concerns, any regulatory framework associated with use of human-animal chimera or hybrid embryos in research should be transparent and workable. (Paragraph 42)

3. The Government agrees with the views of the Committee regarding appropriate regulation. In the proposed draft Human Tissue and Embryos Bill, it is envisaged that the Regulatory Authority for Tissue and Embryos will provide workable and transparent regulation of inter-species embryo research.

Recommendation 3

We are of the opinion that ethical and moral concerns should be considered within the context in which they are made, and that inappropriate use of science to justify ethical and moral arguments is unhelpful. Inappropriate use of science should be identified and disregarded by Government and other policy-makers. (Paragraph 43)

4. The Government agrees that it is important to use evidence appropriately in areas that are a complex amalgam of ethics, moral beliefs and science, such as this field of research.

Recommendation 4

In line with the recommendation of the previous Science and Technology Committee, we recommend the creation of a new Parliamentary standing Committee on Bioethics. (Paragraph 44)

5. The Government continues to share the Committee's views on the value of airing and debating bioethical issues in Parliament. However, the Government maintains its view, as expressed in response to the Committee's previous report, that the creation of a new parliamentary standing Committee on Bioethics is not actually necessary. While developing the draft Human Tissue and Embryos Bill, consideration has been given to providing a level of parliamentary control in the legislation. For example, in developing a flexible and future-proof regulatory system for hybrids and chimeras, the Government also wished to include a role for Parliament to be involved in significant changes to the regulatory controls.

Risk management

Recommendation 5

In the event that research using cytoplasmic hybrid embryos is authorised, we urge the Government to ensure that appropriate risk management procedures are established and implemented. (Paragraph 54)

6. The Government agrees with the Committee that researchers will have to apply appropriate risk management procedures for research that involves the mixing of human and animal materials. We will keep the current procedures under review.

Value of cytoplasmic hybrid research

Recommendation 6

Research, by its very nature, is aimed at enhancing knowledge. Whilst we recognise scientific debate about the potential usefulness of cytoplasmic hybrid embryos in research, we do not believe that the existence of differing views of whether a methodology is workable before it has been sufficiently tested is reason enough to prohibit such research from taking place. (Paragraph 57).

Recommendation 7

We recognise the scientific debate among experts about the potential usefulness of the research under discussion in this Report but we conclude that the scientific community as a whole is supportive of the work being licensable, even where there may be doubts about its likely success. (Paragraph 58)

7. The Government agrees that prohibitions upon research should not be based solely on the workability of the methodology. The Government continues to believe that a regulatory authority should assess whether research is necessary or desirable, taking into account, amongst other things, the quality of the scientific rationale for the research.

Importance of research involving cytoplasmic hybrids

Recommendation 8

We believe that the creation of human-animal chimera or hybrid embryos, and specifically cytoplasmic hybrid embryos, is necessary, for example in the pursuit of knowledge about the genetic basis of disease and the direction of stem cells into future cell-based therapy. Furthermore, we recognise that stem cells produced through this methodology may be useful in drug discovery and that they may lead to the eventual reduction of animal use, for example in toxicity testing. (Paragraph 59)

Recommendation 9

We believe that use of animal eggs in the creation of cytoplasmic hybrid embryos will help to overcome the current shortage of human eggs available for research and that use of animal eggs is required to enable researchers to develop the practical techniques which may be required for eventual production of cell-based therapy through this method using human eggs. (Paragraph 60)

8. We are grateful to the Committee for further elucidating these arguments, for examining the evidence, and for presenting their views of the necessity of this research. We share the Committee's desire for the ends listed, such as the use of stem cells in drug discovery. We ask the Committee to note that our White Paper proposals were intended to clarify the legislative position of such inter-species embryos, and to open the door to research using them through regulations as necessary.

The role of the Human Fertilisation and Embryology Authority in regulating research

Recommendation 10

We agree with HFEA that the wider issue of whether human-animal chimera or hybrid embryos should be allowed for research should be decided by Parliament. However, it is the role of HFEA to make judgements in areas considered within the spirit of the HFE Act where its legal advice indicates that it is reasonable to do so. Not to do so undermines the effectiveness of an independent regulator. (Paragraph 64)

Recommendation 11

We support the decisions of the HFEA Scientific and Clinical Advances Group, Ethics and Law Committee and Horizon Scanning Group that an embryo containing human nuclear DNA and mitochondria of animal origin should be regarded as a human embryo for the purposes of the 1990 HFE Act. (Paragraph 68)

Recommendation 13

We support the decision of the HFEA that research involving the creation of cytoplasmic hybrid embryos would probably fall with the remit of the HFEA to regulate and license and would not be prohibited by current legislation. Although we have received submissions from those who do not believe that this is the case, the weight of scientific and legal argument is in favour of treating these embryos as human. We accept that this decision might leave the HFEA open to legal challenge that it was acting *ultra vires* in considering the applications. However, given the accepted desirability for legal clarification in this area, we view legal challenge as highly likely but also potentially helpful in establishing the limits of the HFEA's remit. (Paragraph 72)

Recommendation 15

We view public consultation in this area as valuable. However, we are of the opinion that this exercise should have been undertaken when the HFEA first received information to indicate that applications for licensing the creation of human-animal chimera or hybrid embryos could be expected. (Paragraph 76)

Recommendation 16

While we agree with the HFEA that the general issues of hybrid and chimera embryos should be dealt with by Parliament, we consider that it is the role of the HFEA to deal with the applications for the creation of cytoplasmic hybrid embryos under current legislation with due speed and process. (Paragraph 77)

Recommendation 17

We agree that there is a need for revised legislation, decided by Parliament, to regulate for current developments in the creation of human-animal hybrid and chimera embryos and to provide a future framework under which regulatory authorities can operate. (Paragraph 78)

9. The Government acknowledges that whether research involving the creation of inter-species embryos should be permitted is generally something that Parliament should decide and that clarification on the issue of inter-species embryos is desirable. In the White Paper, the Government stated its intention to clarify the extent to which law and regulation applies to inter-species embryos. The pre-legislative scrutiny of the draft Bill and the introduction of the Bill proper will give Parliament opportunities to determine the legislation on this issue.

10. Until the introduction of revised legislation, the HFEA has to consider the applications under current legislation. We agree with the Committee that a legal challenge to the HFEA's decision may well be made, and that, it might lead to the courts clarifying the extent of the HFEA's remit under current legislation.

11. In considering the applications, the HFEA has taken advice from its subcommittees, the Scientific and Clinical Advances Group and the Ethics and Law Committee, which advised that inter-species embryos, specifically cytoplasmic hybrids, could be considered to be embryos for the purpose of the 1990 Act. The legal advice obtained by the HFEA from Queen's Counsel stated that cytoplasmic hybrid embryos would 'probably' fall within their remit.

12. Although there is not absolute clarity about whether or not inter-species embryos fall within its remit, the HFEA aims to make a policy decision on licensing inter-species embryos at its meeting in September 2007, therefore fulfilling its role as a regulator. Although the HFEA identified the potential issue of inter-species embryos earlier, and therefore could have embarked upon public consultation prior to receipt of an application, the Government accepts that with finite resources the HFEA had to prioritise its workload as it considered appropriate. The HFEA gave active consideration to this general issue before receiving the specific applications. As soon as the applications were received, the Authority considered the issue at its next scheduled meeting, in January 2007, and committed to carrying out an extensive consultation within a relatively short time. Although this has resulted in delayed consideration of the application, it has allowed the period of public consultation which has been welcomed by the Committee (recommendation 34).

Viability

Recommendation 12

We understand that some form of viability test will have been subject to the legal advice sought by the HFEA on this issue. Nevertheless, we have grave scientific concerns about its validity. We do not believe that it is appropriate to use viability as a mechanism for determining whether or not a creation is human, particularly since attempts to prove viability through implantation in a uterus would be unlawful. Furthermore, were the viability test to be failed, this would mean that such research would be completely unregulated, which case law has found to be unsatisfactory. (Paragraph 71)

13. For the reasons stated by the Committee, the Government and the HFEA agree that the question of 'viability' should not determine whether a creation falls within the definition of an embryo in the 1990 Act, i.e. is a live human embryo. However, the only case law available looking at the meaning of 'live' in this context did consider whether the embryo had 'the normal potential to develop', for which 'viability' has been used as a shorthand. Given the possibility of a legal challenge to a decision that inter-species embryos fall within the scope of the 1990 Act, it is therefore right that the HFEA considers the question of 'viability' as part of its evidence gathering.

Publication of Human Fertilisation and Embryology Authority legal advice

Recommendation 14

It would have aided transparency and public and parliamentary debate on this subject if the HFEA's legal advice had been published. (Paragraph 75)

14. The Government agrees that it would have aided transparency if the HFEA had been in a position to publish its legal advice. However, as the Committee is aware, there were sound reasons relating to the risk of legal challenge as to why it was not appropriate. The legal advice was shared with the Committee in confidence to inform their own consideration.

Pre-legislative scrutiny

Recommendation 18

We support the Government's intention for pre-legislative scrutiny of the draft Bill and encourage the Government to take advantage of all possible sources, including this Report and that of our predecessor Committee, to inform the debate. (Paragraph 79)

15. The Committee will now be aware that the pre-legislative scrutiny committee has now been formed from members of both Houses. We will draw any relevant sources, including these reports, to the attention of the scrutiny committee.

Definitions

Recommendation 19

We are critical of the Government for not clearly setting out areas of research practice intended to fall under the proposed legislation. Much confusion has thus been caused. However, we accept that this lack of clarity may result from the lack of understanding more generally with regard to the potential for this area of research and what the term 'human-animal chimera or hybrid embryos' may cover. We welcome moves by the Academy of Medical Sciences to address this problem and we urge the Government to work with the Academy, HFEA and other stakeholders to ensure that the scope of research practice intended to be covered by legislation is clearly defined in the draft Bill. (Paragraph 85)

16. The Government accepts the views of the Committee on the importance of definitions when communicating policy intentions to the public. This is a complex area of science, and evidence presented to the Committee during the inquiry highlighted the lack of consensus on appropriate terminology. We, like the Committee, welcome the opportunity to work with the Academy of Medical Sciences and other stakeholders on any necessary refinement of terminology, particularly in the content of the draft Bill. It was always our intention to be more specific about 'hybrids' in the draft Bill than in the White Paper, which we have done.

Government proposals

Recommendation 20

We find the Government proposals in the White Paper unnecessarily prohibitive and recommend the Government ensure that its draft Bill reflects the liberal view it claims to be taking in opening the door to research using human-animal chimera or hybrid embryos. (Paragraph 88)

Recommendation 21

We believe that there is a need to allow research using some forms of human-animal chimera or hybrid embryos, including but not exclusively cytoplasmic hybrid embryos, to proceed immediately. We recommend that the Government propose draft legislation which is immediately permissive, through regulation, to those areas of research it deems acceptable. (Paragraph 90)

Recommendation 26

We have made it clear that we regard the current Government proposals as overly prohibitive and that there should be regulation of this research area through licensing. The new legislative structure should permit the creation of animal-human hybrid and chimera embryos for research purposes, subject to regulation, and should aim to reduce the risk of litigation on borderline cases. (Paragraph 99)

Recommendation 27

We recommend that the Government proposals in the Bill for the regulation of the creation of animal-human chimera and hybrid embryos be based on the legislative structures outlined in paragraph 100 of this Report. (Paragraph 102)

17. In the White Paper setting out the proposals for revised legislation published prior to this draft Bill, the Government stated that the Bill would clarify the extent to which regulation would apply to embryos containing both human and animal material. The White Paper also proposed that the creation of hybrid and chimera embryos *in vitro* should not be permitted but that there should be a regulation-making power allowing exceptions to the prohibition. The Bill as currently drafted for pre-legislative scrutiny reflects this position.

18. Having regard to the scientific evidence produced during the Committee's inquiry, and acknowledging that the recommendations are a consensus view of the Committee, we intend to accept the principle that legislation should provide for the following inter-species entities, as listed in clause 17(2) of the draft Bill, to be created for research purposes, subject to the usual requirements for embryo research in the 1990 Act (i.e. that the research is necessary or desirable):

    - Cytoplasmic hybrid (cybrid) – 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.
    - Human transgenic embryos – a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal.
    - Human-animal chimera – a human embryo that has been altered by the introduction of one or more animal cells.

19. This list includes the cytoplasmic hybrids that the Committee particularly wants to see allowed, but does not include 'true' hybrids created from mixing human and animal gametes, other than as currently permitted for the purpose of testing the fertility or normality of human sperm. This recognises the need to draw a line between what is and is not acceptable, which the Committee sees as useful (paragraph 91 of the report). The draft Bill, however, currently allows the scope for Parliament to allow the creation of 'true hybrids' through secondary legislation, in the light of evidence that they are necessary.

14-day rule

Recommendation 22

We believe that, in general, the creation of all types of human-animal chimera or hybrid embryos should be allowed for research purposes, if appropriately regulated. However, in line with the recommendation of the previous Committee, we see no benefit from allowing the development of human-animal chimera or hybrid embryos past the 14-day stage *in vitro* and recommend that such practice is not licensed unless it is proved necessary. (Paragraph 93)

20. The draft Bill proposes to maintain the prohibition upon keeping human embryos in culture for more than 14 days.

21. However, some inter-species embryos created by altering the cellular or genetic composition of a human embryo could fall within the remit of the Animal (Scientific Procedures) Act 1986 before 14 days has elapsed where, because of the presence of animal nuclear DNA, they are deemed to be protected animals for the purposes of the 1986 Act.

22. Under the 1986 Act, a mammalian embryo becomes a protected animal at the halfway point of its gestation period. If the cells and/or genes of two species are present, then it would be the shorter of the two gestation periods that is used as the basis for this calculation. For example, since the gestation period of a mouse is approximately 19 days, a human-mouse chimera or hybrid embryo containing mouse nuclear DNA could fall under the protection of the 1986 Act after 9.5 days.

23. Clause 17(2) of the draft Bill therefore proposes that no inter-species embryo may be allowed to develop to a stage at which regulation under the Animal (Scientific Procedures) Act 1986 would begin. This avoids the risk of the dual regulation of some inter-species embryos by both the Home Office and the Authority, assuming the creation of these inter-species embryos is permitted by the Bill proper.

24. At the present time, because of prohibitions in the 1990 Act regarding the use of human embryos, this kind of research could not begin, and thereby reach the stage at which it would be subject to consideration by the Home Office. The draft Bill does not prevent research which is currently licensable under the 1986 Act, e.g. the creation of transgenic mice containing some human genes.

Implantation in a woman

Recommendation 23

In line with the recommendations of the previous Science and Technology Committee, we recommend that legislation prohibit the implantation of human-animal chimera or hybrid embryos in a woman. (Paragraph 94)

25. Clause 16 of the draft Human Tissue and Embryos Bill maintains the Government's position that no entities other than embryos created by the fertilisation of a human egg with a human sperm should be permitted to be placed in a woman.

Human embryonic stem cell research

Recommendation 24

We recommend that care be taken by the Government to ensure that the draft Bill does not prohibit research using human embryonic stem cell lines where such research is currently regulated through the Animals (Scientific Procedures) Act 1986. (Paragraph 96)

Recommendation 25

We recommend that legislation allow for regulation of the implantation of human stem cells, whether created from human embryos or human-animal chimera or hybrid embryos, into animal blastocysts. (Paragraph 98)

26. Dialogue across Government, specifically between the Department of Health and the Home Office, has been maintained throughout the development of the draft Bill, to ensure that no research which might be licensable under the Animal (Scientific Procedures) Act 1986 is affected by proposals in the draft Human Tissue and Embryos Bill. This includes animal-human chimeras created by the insertion of human cells, including embryonic stem cells, into an animal blastocyst.

UK research

Recommendation 28

A ban and the prospect of a ban in draft legislation on human-animal chimera or hybrid embryos would undermine the UK's leading position in stem cell research and the international reputation of science in the UK. (Paragraph 104)

Recommendation 29

We are concerned that a ban or a proposed ban may not only encourage researchers to leave the UK in order to undertake their research in a more permissive regulatory regime, but it may also inhibit early stage researchers entering the field. Whilst we do not believe that UK competitiveness should dictate policy in a research area, we believe that the Government should consider this as a contributory factor and we recommend that the Government ensure that it is properly briefed on potential implications from future legislation in this area. (Paragraph 107)

27. The history of public policy in this area is one of clear opposition to the creation of embryos crossing the species divide – this thread runs through the original Warnock report,[6] the 1990 Act, and the policy papers that preceded it.

28. In 2000, when the Chief Medical Officer's expert group on stem cell research advised that 'the mixing of human adult cells with the live eggs of any animal species should not be permitted', the Government undertook a commitment to put this prohibition into legislation when parliamentary time allowed. This was the Government's expressed position prior to its 2005 consultation.

29. The Government White Paper, *Review of the Human Fertilisation and Embryology Act*, proposed policies that opened the door to this kind of research and moved Government policy away from permanent prohibition. The draft Human Tissue and Embryos Bill proposes that certain inter-species embryo research should not be prohibited but brought within a regulatory framework.

6 Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, ISBN 0101931409. Referred to hereafter as the Warnock report.

Public awareness/engagement

Recommendation 30

Public awareness of the need for and benefits of research in this area should be encouraged, alongside an understanding of the reasons for the requirement to update legislation. We regard it as the responsibility of the Government and HFEA to keep the public informed in respect of developments in legislation related to the creation of human-animal chimera and hybrid embryos for research. (Paragraph 108)

Recommendation 32

We find it unhelpful that witnesses on both sides of the argument have claimed to represent the public view, where supporting evidence for this is lacking. (Paragraph 113)

Recommendation 33

Accomplishing effective public engagement in this debate may be difficult, but significant effort must be made to this end. We believe that additional education is required to enhance public understanding of the techniques proposed by this area of research and its associated potential achievements and problems, including scientific, ethical and moral concerns. (Paragraph 114)

Recommendation 34

Notwithstanding the accompanying delay in consideration of the King's College London and Newcastle University research applications, we welcome the HFEA proposed consultation on general principles and commend steps taken by the Authority to ensure appropriate drafting. We also commend the Government for allowing funding to be allocated toward education in this area. (Paragraph 115)

30. The Committee will be aware that the HFEA is presently undertaking a public consultation on the creation of inter-species embryos for research under the current legislation. The Government agrees with the Committee about the importance of public awareness of the needs and benefits of this research and welcomes the consultation that the HFEA is undertaking. The Government is supporting the public dialogue element of this consultation through the Department of Trade and Industry's Sciencewise Programme to ensure that public understanding in this area is maximised.

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