HM Government

Human Reproductive Technologies and the Law

Government Response to the Report from the House of Commons Science and Technology Committee

Cm 6641

Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
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Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law

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1 Numbers in parentheses refer to the conclusions and recommendations of the Science and Technology Committee, as listed in their report, pp. 175 to 189.

Foreword

On 24 March 2005, the House of Commons Science and Technology Committee published a report on '*Human Reproductive Technologies and the Law*', following a yearlong inquiry and collection of evidence[2].

The Government welcomes the Select Committee's report as an important contribution to public debate on the future regulation of human reproductive technologies in the UK[3]. Whilst the report starts from the position that "assisted reproduction and research involving the embryo of the human species both remain legitimate interests of the state",[4] it presents an opportunity for debate on the nature and proper bounds of those interests and the means by which they may best be secured.

The Select Committee's conclusions and recommendations have been considered in the context of the Government's own plans to review the Human Fertilisation and Embryology Act 1990 (the HFE Act), announced on 21 January 2004. In deciding to undertake a review, the Government made clear that whilst recognising that the HFE Act has worked well and continues to do so, we were prepared to look at whether the Act needs to be updated, and if so, how. The development of new procedures and technologies in assisted reproduction, the profound ethical issues associated with them, changing public perceptions, and international developments in the standards that clinics have to meet, were all issues that led us to conclude that a review of the HFE Act was necessary.

This paper sets out the Government's response to all of the report's 104 conclusions and recommendations. Recommendations addressing the same issue have been grouped together where appropriate. In several cases we have indicated that we will seek wider public views on the Committee's recommendations as part of our own review of the Act.

2 Fifth Report of Session 2004-05, HC 7-I. Oral and written evidence published as HC 7-II.
3 The Government also notes publication of the Select Committee's Eighth Special Report of Session 2004-05 (HC 491), recording the disagreement of five Committee members with the main report.
4 Recommendation 2, paragraph 46, of the Select Committee's report.

Response to the Committee's conclusions and recommendations

Status of the embryo

Recommendation 1

While it has been argued that there have been many scientific developments and changes in social attitudes, the Warnock Committee's approach to the status of the embryo remains valuable. While this gradualist approach to the status of the embryo may cause difficulties in the drafting of legislation, we believe that it represents the most ethically sound and pragmatic solution and one which permits in vitro fertilisation and embryo research within certain constraints set out in legislation. (Paragraph 28).

1. The Government notes the Committee's support for the gradualist approach to the status of the human embryo as originally proposed by the Warnock Committee in 1984[5] and agrees that this approach continues to be appropriate.

2. When announcing its own review of the HFE Act, the Government said that it did not intend to open up fundamental aspects of the law. The Government therefore has no plans to bring forward any proposals that would alter the legal status of the human embryo.

Recommendation 2

We accept that in a society that is both multi-faith and largely secular, there is never going to be consensus on the level of protection accorded to the embryo or the role of the state in reproductive decision-making. There are no demonstrably "right" answers to the complex ethical, moral and political equations involved. We respect the views of all sides on these issues. We recognise the difficulty of achieving consensus between protagonists in opposing camps in this debate, for example the pro-life groups and those advocating an entirely libertarian approach to either assisted reproduction or research use of the embryo. We believe, however, that to be effective this Committee's conclusions should seek consensus, as far as it is possible to achieve. Given the rate of scientific change and the ethical dilemmas involved, we conclude, therefore, that we should adopt an approach consistent with the gradualist approach, of which the Warnock Committee is one important example. This does not mean that we will shy from criticism of regulation to date, where we believe it warranted. But it does mean that we accept that assisted reproduction and research involving the embryo of the human species both remain legitimate interests of the state. Reproductive and research freedoms must be balanced against the interests of society but alleged harms to society, too, should be based on evidence. (Paragraph 46).

5 Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, ISBN 0101931409.

3. In common with the Select Committee, the Government recognises a diversity of deeply held ethical, religious and political views on issues associated with human reproductive technologies, and therefore welcomes the Committee's explicit aim to achieve consensus in this area so far as possible.

Recommendation 98

Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety. Intending parents should be able to seek appropriate services, subject to the professional regulation of safety and quality. This would ensure that reproductive decisions remain primarily in the private domain, governed by professional ethics and the law of consent. However, legislation will be needed to offer appropriate protection for the human embryo and to accommodate status and other legal issues. (Paragraph 391).

4. The Government agrees that assisted reproduction is now a common clinical procedure. The birth of the first child conceived through IVF took place over twenty-five years ago, and a growing range of assisted reproduction techniques are being practised on an increasing scale. In January 2004 the Government announced its intention to undertake a review of the HFE Act to ensure that the Act remains effective in the 21st century. This will take into account possible changes in public perceptions as well as factors such as the development of international safety standards that clinics have to meet. The Government is committed to the principles of good regulation, which include ensuring that regulation is proportionate and appropriately targeted. We agree that legislation remains necessary, in particular to provide appropriate protection for the human embryo.

Precautionary Principle

Recommendation 3

We do not see why the area of human reproductive technologies should do anything other than proceed under a precautionary principle currently prevalent in scientific, research and clinical practise. This means – as specified in paragraph 46 above – that alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded. (Paragraph 47).

5. The Government agrees that reproductive and research freedoms must be balanced against the interests of society, and that the area of human reproductive technologies should proceed under a precautionary approach.

6. The Government disagrees, however, with the Committee's interpretation of the precautionary principle. The potential harms that should be taken into account may not necessarily be susceptible to demonstration and evidence in advance. For example, in our view the application of a precautionary approach requires that consideration of harms to society or to patients must include the consideration of potential harms to future offspring.

7. The Government believes that the utmost attention should be given to the welfare of children born as a result of assisted reproduction, particularly in deciding whether to approve novel and experimental technologies.

Embryo research

Recommendation 4

We believe that research on human embryos can be undertaken without compromising their special status but that this research should have proper ethical oversight as set out in Chapter 8 and 9. We further conclude that, where necessary, embryos can be created specifically for research purposes. (Paragraph 50).

8. In announcing its own review of the HFE Act, the Government stated that it did not intend to reopen the issue of the permissibility of research using human embryos, as this had been extensively and conclusively debated in Parliament in recent years. Parliament decided to allow embryo research, on a free vote, during the passage of the HFE Act, and voted in 2001 to extend the purposes for which such research could be undertaken to include research into developing treatments for serious diseases.

9. The Government therefore concurs with the Committee that research using human embryos, including where necessary the creation of embryos for research, can be undertaken subject to appropriate ethical oversight.

Recommendation 59

We welcome the efforts that the HFEA has made to improve its research licensing procedures and we hope that these prove effective. However, we believe that there needs to be a thorough analysis of the process by which research involving embryos is approved so that we do not lose sight of what the process is trying to achieve. (Paragraph 242).

10. The Government accepts the need to ensure that legitimate research is able to thrive within appropriate safeguards. We welcome the Committee's recognition of efforts by the HFEA to improve its research licensing procedures. However, we accept that measures to minimise bureaucratic burdens and remove overlapping responsibilities wherever possible should be given further consideration and we will look into this.

Recommendation 83

We recognise that there need to be some prohibitions on research in law, as we set out in Chapter 9, but we think there is much merit in a system of local oversight to provide faster, more proportionate, oversight of research on human embryos. (Paragraph 341).

Recommendation 100, part (g)

[The regulator will] ensure that research proposals have received adequate ethical and scientific review and publish a lay summary of all approved research projects covered by the legislation. (Paragraph 394).

Recommendation 104

Embryo research would need to be undertaken in an accredited facility, have been scrutinised by a local or regional research ethics committee, which would ensure that adequate consent had been sought from donors, and have been scientifically peer reviewed. (Paragraph 400).

11. The Government notes the Committee's view that there should be a system of local approval of research projects involving human embryos, subject to oversight by a national regulator. However we do not accept this proposal. We would have serious reservations about the consistency of decision-making, the expertise available, and the clarity of responsibilities in such a system.

12. The Government believes that the purposes for which research using embryos may legitimately be undertaken should, as now, be determined by Parliament and that research projects should continue to be approved by a national body in order to ensure compliance with the law, national consistency and appropriate ethical oversight.

Definition of embryo

Recommendation 5

We are concerned that any legal definitions of the embryo based on the way it was created or its capabilities would either be open to legal challenge or fail to withstand technological advance. The attempt to define an embryo in the HFE Act has proved counter-productive, and we recommend that any future legislation should resist the temptation to redefine it. We consider that a better approach would be to define the forms of embryo that can be implanted and under what circumstances. Using this approach, only those forms of embryo specified by the legislation, such as those created by fertilisation, could be implanted in the womb and thereby used for reproductive purposes. Other forms of embryo would be regulated insofar as they are created and used for research purposes. (Paragraph 53).

Recommendation 99

The legislation will not define the embryo, although it will not come under the protection of the law until it has reached the two cell stage after around 36 hours. It will introduce a definition of gamete to encompass all haploid human cells but a distinction will be made between mature gametes on one hand and immature and artificial gametes on the other. Only embryos created through the union of human sperm and egg can be implanted in a woman, unless otherwise specified. Embryos formed by any process identified in the legislation must be destroyed at a specified stage of development if they are not implanted in a woman. This stage should be set at 14 days but this should be capable of amendment by Parliament. Research on any embryo containing human chromosomal material is permissible up until the specified stage of development if it has received approval from a local research ethics committee and—where appropriate—peer review from a public research funding agency. (Paragraph 392).

13. The Government is aware of the potential pitfalls associated with attempting to frame legal definitions in an area of fast-moving science, and welcomes the Committee's helpful suggestions in this area. The Government agrees that there may be merit in the approach of specifying in legislation those forms of embryo which may be implanted, and otherwise regulating the use of embryos in research according to the normal usage of the term. We intend to consult further on this approach in our review of the HFE Act.

Recommendation 6

We see little value in regulating the use of an egg in the process of fertilisation. A unique genetic entity is only formed at the union of the male and female pronuclei and this seems the most appropriate point at which to bring the creation under the protection of legislation. (Paragraph 55).

14. The Committee's recommendation to remove human eggs in the process of fertilisation from the scope of regulation appears to be motivated primarily by concern that the current range of prohibitions in the HFE Act have prevented certain types of research on the early embryo. The Government is not persuaded that re-defining the point at which regulation of the embryo begins is necessarily an appropriate response to those concerns, which are also addressed more specifically in the Committee's recommendation 14. The Government will, however, seek wider public views on the issue of the appropriate starting point of regulation, and any unintended consequences and loopholes which could arise from alteration of the current position.

Recommendation 7

We have been told that the 14-day rule is an arbitrary cut off point. For many, even those who support assisted reproduction and embryo research, an extension to the 14-day rule would be unacceptable. We accept that there is no case at present for an extension, or indeed reduction. However, we believe that, if scientists or clinicians were able to provide convincing justification for any change, this should be determined by Parliament. (Paragraph 58).

15. The Government agrees that there is no case at present for changing the 14-day limit on keeping or using an embryo, and that any change to this position should be a matter for Parliament.

Placing a human embryo in an animal

Recommendation 8

In considering the subject comprehensively we should not shy away from addressing difficult subjects which may widely be considered 'taboo'. In this instance, however, we have heard no evidence which would lead us to conclude that there is any merit in relaxing the HFE Act's prohibition on placing human embryos in an animal for research purposes. Should the government receive expert advice to the contrary, given the ethical issues involved, any such change should be a matter for Parliament and primary legislation. (Paragraph 62).

16. The Government has heard no compelling evidence that there is any good reason to remove the prohibition on placing human embryos in animals. This is currently prohibited in the HFE Act and we have no intention of changing this.

Chimeras and hybrids

Recommendation 9

The ethical status of hybrids and chimeras is complex. While there is revulsion in some quarters that such creations appear to blur the distinction between animals and humans, it could be argued that they are less human than, and therefore pose fewer ethical problems for research than fully human embryos. We recognise concerns that hybrids and chimeras could be used for reproductive purposes and recommend that new legislation a) defines the nature of these creations, b) makes their creation legal for research purposes if they are destroyed in line with the current 14-day rule for human embryo cultures, and c) prohibits their implantation in a woman. (Paragraph 66).

17. The Government agrees that the issue of hybrids and chimeras is complex. Currently, the mixing of human and animal gametes is only allowed (under licence) for testing the fertility or normality of human sperm, and the product of the mixed gametes must be destroyed when the test is complete and no later than the two cell stage. The Government will seek wider public views on whether there is a compelling case for the greater use of hybrid or chimera embryos in research. However, we agree with the Committee that there would need to be strong legal safeguards on such research, in particular that they could not be implanted in a woman and that they must be destroyed within 14 days.

Reproductive cloning

Recommendation 10

We recognise that human reproductive cloning, if possible at all, is not currently safe and that no clinician could legitimately pursue it under existing professional regulation. In addition, we recognise that research in developing reproductive cloning would very likely involve experimentation that is highly unethical. Nonetheless, the patchy legislation around the world suggests that the research will take place somewhere and someone may be able to demonstrate a technique that is safe, effective and reliable. (Paragraph 69).

18. The Government agrees with the Committee that reproductive cloning is currently unsafe. The most widely accepted view is that cloning causes aberrant gene expression during development. Cloned animals display a range of abnormalities. Most are lost before birth, and those that are born suffer from a disproportionately high number of deficiencies. Even if all of the safety issues in animal cloning were to be resolved in the future by research in animals, reproductive cloning in humans would still carry enormous and unknown risks, some of which would be likely to be long-term.

19. In the absence of any obvious potential benefit to humanity that would be uniquely delivered by human reproductive cloning, we see no circumstances in which human reproductive cloning could be justified or allowed.

Recommendation 11

Even if human reproductive cloning were shown to be safe, effective and reliable we would still have grave concerns about many of its applications. However, there are clear examples where the situation is not so clear-cut and the ethical debate is highly complex. Professor Ian Wilmut has described a scenario in which the aims are therapeutic and no clone is created of an individual who has ever been born. If there is to be a total prohibition of any form of reproductive cloning, it is important that it is supported by principled arguments why such a technique should be banned even if it were shown to be safe, effective and reliable. Without such arguments, an indefinite absolute ban could not be considered rational. The Minister's refusal to enter into any discussion of reproductive cloning is not an encouraging starting point for an open-minded review of the adequacy of existing legislation. (Paragraph 71).

20. The Government disagrees with the Committee that there is any significant case for re-opening the debate on reproductive cloning. As recently as 2001, it was discussed extensively in both Houses of Parliament and national legislation was introduced which is clear on this matter[6]. Attempts to place an embryo, created other than by fertilisation, in a woman carries a ten year prison sentence and/or an unlimited fine.

21. There is also a strong international consensus that human reproductive cloning is morally repugnant. Numerous respected international committees on bioethics, including UNESCO, the Council of Europe and WHO, as well as the UN General Assembly, have considered the issue and concur that reproductive cloning should be proscribed.

6 The assertion in paragraph 71 of the Committee's Report, repeated in paragraph 213, that "it was the Government's earlier intention that it [reproductive cloning] should remain a legal but licensable activity" is incorrect. Given the emergence of cloning technology, the Government at the time (2000: Government response to the Chief Medical Officer's Expert Group Report on Stem Cell Research) took the view that the creation of embryos through the use of cloning techniques was covered by the HFE Act and therefore an effective prohibition was imposed through the HFEA's licensing powers. The Government made a commitment to put this ban in primary legislation when Parliamentary time allowed. This commitment was met by the Human Reproductive Cloning Act 2001. The House of Lords confirmed in 2003 that embryos created by therapeutic cloning are within the regulatory remit of the HFE Act.

Embryo splitting

Recommendation 12

As with cell nuclear replacement, the risks of implanting a split embryo are high, but a distinction needs to be made between the safety of the treatment and the fundamental ethical principles. If embryo splitting for treatment purposes is to be prevented, as with reproductive cloning, this should be based on coherent ethical argument, such as the right not to be purposefully created with a specific genetic identity. (Paragraph 75).

22. The Government agrees with the Committee that the risks associated with implantation of a deliberately split embryo are high and believes that safety concerns are currently sufficient to preclude the use of embryo splitting in assisted reproduction treatment. The Government is not aware of any potential benefits from embryo splitting that would justify a change to this position.

Parthenogenesis

Recommendation 13

We regret that the use of parthenogenesis to derive stem cells was not considered by either the Donaldson report or the House of Lords Stem Research Committee. This gives the impression that inadequate consideration has been given to these ethical issues before research projects were licensed by the HFEA. Nevertheless, we are pleased that this line of research is possible under the current legislation as we take the view that parthenogenesis raises fewer ethical issues than creating an embryo using CNR, provided that it is not cultured for longer than 14 days. (Paragraph 77).

23. Embryos created by parthenogenesis are within the scope of regulation under the HFE Act, and their creation and use for projects of research within the purposes laid down by Parliament may currently be licensed by the HFEA. Such projects may, for example, include the derivation of embryonic stem cells for the purpose of increasing knowledge about serious diseases or enabling such knowledge to be applied.

24. The Human Reproductive Cloning Act 2001 bans the use of embryos created by parthenogenesis for reproductive purposes, as was made clear during the passage of that Act. The Government has no plans to change the position with regard to parthenogenesis.

Research on mitochondrial diseases

Recommendation 14

Regardless of whether cell nuclear replacement is undertaken on eggs or embryos for the purposes of research on mitochondrial diseases, the aim of the research is the same. Given that we permit experimentation on embryos to investigate heritable diseases, we see no need to distinguish between the techniques in law. (Paragraph 80).

25. Cell nuclear replacement (CNR) is a technique currently used in the creation of embryos for research, by inserting the nucleus of an adult cell into an egg that has had its nucleus removed. This is known as therapeutic cloning and is allowed under licence from the HFEA. Using an embryo created in this way for reproductive purposes is prohibited.

26. The HFE Act does not prohibit research on eggs and therefore does not prohibit the use of the CNR technique to develop understanding of and treatments for mitochondrial diseases in eggs. Use of the CNR technique for research on an embryo would fall foul of the prohibition in the HFE Act on altering the genetic structure of a cell while it forms part of an embryo.

27. The Government agrees with the Committee that research undertaken on embryos using the cell nuclear replacement technique for the purpose of studying mitochondrial diseases should be permissible in law, and will consult on amending the law accordingly.

Genetic modification

Recommendation 15

Effective and safe germline therapy to treat serious genetic diseases would result in reduced child mortality and morbidity and fewer abortions and destroyed embryos. (Paragraph 81).

Recommendation 16

We conclude that the absolute prohibition on genetic modification of the pre-14 day human embryo should be removed for research purposes and recommend that future legislation, while prohibiting the modification of chromosomal DNA for reproductive purposes, should provide for regulations to be made to relax this ban under tightly controlled circumstances if and when the technology is further advanced. (Paragraph 82).

28. The Government accepts that in theory, germline gene therapy or genetic modification of embryos could be used to prevent the transmission of harmful gene variations to subsequent generations. If it could be done safely, such therapies might be a way of repairing gene defects before clinical manifestations, which would also spare descendants the burden of serious genetic diseases.

29. However, the potential use of therapies which would involve deliberate germline therapy or genetic modification of embryos clearly raise fundamental ethical issues on which there are likely to be a diversity of views, and safety concerns which demand the most stringent precautionary approach.

30. The Government accepts the Committee's recommendation for the continuance of the prohibition on genetic modification of embryonic chromosomal DNA for reproductive purposes. The Government believes that there is no case at present for removing this prohibition in view of very serious safety concerns. These concerns are reflected in a range of prohibitions in international agreements and in UK law.

31. The HFE Act already contains a regulation making power in relation to genetic modification of embryos for the purpose of research, and the Government will seek wider public views on making such research permissible directly in primary legislation.

GIFT and IUI

Recommendation 17

If the purpose of regulation in assisted reproduction is to protect patients, there is no justification for exempting GIFT and IUI with partner sperm from the legislative framework. However, given our acceptance of the position that the state should intervene only in carefully defined and justified circumstances, where there are specific harms, in reproductive decisions, the common law rules of consent are sufficient to protect patients in the face of these risks. It is consistent with our ethical approach that, rather than adding to the list of regulated fertility treatments, we should be decreasing the level of state intervention. We accept that GIFT and IUI pose similar risks to IVF, but we have already concluded that these risks lie within accepted legal boundaries on what people can consent to. We have not been persuaded, therefore, that regulation should demand anything more than that the highest technical standards are observed. (Paragraph 83).

32. The safety and quality standards of the EU Tissue Directive[7] will apply to the use of partner sperm in treatment, and therefore the use of techniques such as GIFT (gamete intra-fallopian transfer) and IUI (inter-uterine insemination) using partner sperm will fall within the scheme of regulation when the Directive is transposed into domestic law. The intention is that the HFEA will be the competent authority under the Directive for the regulation of GIFT and IUI.

33. The Government agrees with the Committee that the regulation of GIFT and IUI should as far as possible be limited to technical and safety issues.

Internet services

Recommendation 18

The risks to users and their offspring from an internet sperm donation service need to be established. There is a case for regulating such services to ensure their quality. It is not clear whether they would be covered by the EU Tissue Directive. If not, we conclude that revised legislation should ensure that such commercial services are subject to the highest technical and safety standards. We would also consider it anomalous if gamete donation that is undertaken in a clinical setting required identifying information to be held in a central database but did not if the donor and recipient were "introduced" over the internet. Our concern is to ensure that the safety and quality standards expected of all assisted reproduction technologies are equivalent. (Paragraph 85).

7 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Recommendation 19

We conclude that while it is appropriate that commercial services involving fresh gametes should be subject to regulation, this should not extend beyond seeking to ensure that there are as few anomalies as possible between different options for donor insemination. (Paragraph 88).

34. The Warnock Committee concluded that artificial insemination by donor should be available subject to safeguards, and recommended that the provision of donor insemination services without a licence should be an offence[8]. The HFE Act enacted this recommendation by prohibiting the use of donor gametes in the course of providing treatment services except in pursuance of a licence[9]. Internet "introductory services" are outside of the scope of regulation as they are not covered by the definition of treatment services in the HFE Act.

35. The Government accepts that there is a case for regulating internet sperm donation services to ensure their safety and quality, and in view of anomalies with the legal status of donors and children conceived within licensed services. The Government will consult on the extent to which these services should be brought within the scope of regulation.

Artificial gametes

Recommendation 20

Subject to their safety, we recognise that artificial gametes have potential to treat infertility and reduce the need for gamete donors. It is important that, in the use of any cell cultures for reproductive purposes, the original donors must be traceable and their informed consent obtained. (Paragraph 90).

36. In future it may be possible to create sperm and eggs from adult cells. The Government accepts that, in theory, such artificially created gametes could have the potential to offer new fertility treatments for people who are unable to produce their own sperm and eggs. The Government will consult on whether such artificially created gametes should ever be allowed in treatment, assuming safety concerns were satisfied.

Welfare of the child

Recommendation 21

The requirement to consider whether a child born as a result of assisted reproduction needs a father is too open to interpretation and unjustifiably offensive to many. It is wrong for legislation to imply that unjustified discrimination against "unconventional families" is acceptable. (Paragraph 101).

8 Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cm 9314, July 1984, paragraph 4.16.

9 HFE Act, section 4(1)

Recommendation 22

The State employs social services to protect children from harm. If it has reason to believe that children born as a result of assisted reproduction are at increased risk then healthcare professionals can alert social services at an early stage. Indeed, the law has declined to intervene to protect the welfare of a child not yet born, being satisfied that the foetus in utero cannot be made a ward of court, and that appropriate action could be taken if required following live birth. (Paragraph 103).

Recommendation 23

The exclusive requirement to consider the welfare of the child for fertility treatments where fertilisation takes place outside the woman or involves donated sperm is illogical. If the legislation aims to regulate the treatment of infertility or subfertility then it should cover all forms of interventions. If it wishes to do both then this needs to be clearly stated and justified. (Paragraph 105).

Recommendation 24

The welfare of the child provision discriminates against the infertile and some sections of society, is impossible to implement and is of questionable practical value in protecting the interests of children born as a result of assisted reproduction. We recognise that there will be difficult cases but these should be resolved by recourse to local clinical ethics committees. The welfare of the child provision has enabled the HFEA and clinics to make judgements that are more properly made by patients in consultation with their doctor. It should be abolished in its current from. The minimum threshold principle should apply but should specify that this threshold should be the risk of unpreventable and significant harm. Doctors should minimise the risks to any child conceived from treatment within the constraints of available knowledge but this should be encouraged through the promotion of good medical practice not legislation. (Paragraph 107).

37. The welfare of children who may be born as a result of assisted reproduction treatment is a central tenet of the HFE Act, and one of the key guiding principles which informs the operation of the HFEA and the content of its Code of Practice. This recognises that whereas patients are entitled to sensitive consideration of their wishes, the welfare of children cannot always be adequately protected by concern for the interests of the adults involved.

38. Recommendations 21 to 24 concern the explicit requirement in the HFE Act to take account of the welfare of the child who may be born as a result of assisted reproduction (and any other child who may be affected) before treatment services are provided[10]. This requires a balancing of the rights and interests of parents and children within a context of appropriate professional practice. The HFEA is currently obliged in law to provide guidance to licensed clinics on the interpretation of this provision, and has undertaken a review of its guidance in this area, including a full public consultation.[11]

10 Section 13(5) of the HFE Act.

11 "Tomorrow's Children: A consultation on guidance to licensed fertility clinics on taking in account the welfare of children to be born as a result of assisted conception treatment". HFEA, January 2005.

39. The Government recognises that attempting to frame these matters in national legislation and guidance which pays due regard both to individual circumstances and to the need for objectivity and fairness is extremely difficult.

40. The Government will therefore seek wider public views on how the welfare of children born as a result of assisted reproduction may best be secured.

Eugenics

Recommendation 25

If ensuring that your child is less likely to face a debilitating disease in the course of their life can be termed eugenics, we have no problem with its use. State programmes that impose a genetic blueprint are another matter. They should be outlawed as part of any regulation of assisted reproduction. Use of the word eugenics must not be used as an emotive term of abuse to obscure rational debate. (Paragraph 116).

41. The Government agrees with the Committee that rational debate on the use of human reproductive technologies for the purpose of preventing serious and debilitating diseases is desirable, regardless of the terms used.

42. The Government strongly agrees that the idea of state programmes intended to impose "a genetic blueprint" is repugnant and should never be permitted. We are not convinced that any additional legislation is necessary to achieve this. However we will keep this under review.

Sex selection by abortion

Recommendation 26

It is possible to sex a child using ultrasound and seek a termination and if PGD reduces the demand for abortion then this is a good thing. While we recognise that abortion legislation recognises the right of the woman, our gradualist approach to the status of the embryo leads us to conclude that there is a mismatch between the protection afforded an embryo created in vitro before it is implanted and one at a later stage of development in a woman's uterus. (Paragraph 119).

43. An abortion may only take place on grounds under the Abortion Act 1967, as amended. Abortion on grounds of fetal sex alone is illegal. The sex of an unborn child might, however, be a legitimate factor in considering whether an abortion is justified on the medical grounds specified in the Abortion Act, for example in sex-linked inherited conditions. Similarly, the HFEA's Code of Practice makes clear that licensed centres may only use information derived from preimplantation testing to select embryos of a particular sex for medical reasons. The Government is therefore not convinced that there is a mismatch between the protections afforded to embryos and fetuses in this regard.

Preimplantation Genetic Diagnosis (PGD) and tissue typing

Recommendation 27

We have concerns about the criteria imposed by the HFEA. PGD is limited in that it can only be used to screen out disorders and thus it cannot be used to create "designer babies". We see no reason why a regulator should seek to determine which disorders can be screened out using PGD. Nevertheless, clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements. (Paragraph 124).

Recommendation 28

We conclude that there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within parameters set by Parliament. (Paragraph 129).

Recommendation 60

The regulation of preimplantation testing is highly unsatisfactory. We recognise that the HFEA has legal jurisdiction but this does not mean that it has a duty to regulate its use beyond ensuring that it is performed to the highest standards within statutory boundaries. (Paragraph 244).

Recommendation 61

The development of the HFEA's policy and licensing decisions on preimplantation tissue typing has been highly unsatisfactory. We share the Chair's contentment with its current policy and agree that revised legislation must make it clear that preimplantation genetic diagnosis and preimplantation tissue typing can be undertaken within legal restraints. (Paragraph 251).

44. The Government does not accept that the development of the HFEA's policy on PGD has been "highly unsatisfactory". We consider it appropriate that the HFEA debated the issues at length with the Advisory Committee on Genetic Testing, conducted a joint consultation, and discussed the findings with the Human Genetic Commission. This process resulted in the HFEA's adoption of a cautious approach to the licensing and regulation of PGD. However, we agree with the Committee that it would be preferable if the parameters for PGD were more clearly set out in law. The Government will therefore seek wider public views on the boundaries of acceptable uses of preimplantation genetic diagnosis and preimplantation tissue typing, and on the appropriate scope and nature of regulatory intervention.

Sex selection

Recommendation 29

The UK should carefully consider the current evidence there available now about such imbalances and harms before allowing blanket changes to our laws and regulations on sex selection. (Paragraph 140).

Recommendation 30

The onus should be on those who oppose sex selection for social reasons using PGD to show harm from its use. However, the use and destruction of embryos does raise ethical issues and there are grounds for caution. The issue requires greater analysis than has been afforded it by the HFEA and we urge greater efforts to establish the demographic impacts across all sectors of society and the implications for the creation and destruction of embryos in vitro before new legislation is introduced. On balance we find no adequate justification for prohibiting the use of sex selection for family balancing. (Paragraph 142).

45. The Government is aware of public concerns about the possible use of sex selection techniques for social reasons. The HFEA's Code of Practice makes clear that licensed clinics may not use any information derived from tests on an embryo, or any material removed from it or from the gametes that produced it, to select embryos of a particular sex for social reasons. The Government has no plans to alter this position to allow sex selection other than for compelling medical reasons. However we will seek wider public views on whether sex selection for family balancing purposes[12] should be permitted, as recommended by the Committee.

Donors

Recommendation 31

We recommend that the Government clarify the position relating to any financial obligations of donors before 1990. It would be regrettable if such donors did not come forward under the mistaken impression that they would become financially liable for the upbringing of children born as a result of an altruistic donation. (Paragraph 150).

46. The Government has set up a pilot scheme for people who donated prior to the Human Fertilisation and Embryology Act 1990 to enable them to put their name on a voluntary contact register, UK DonorLink, if they wish. We will assess the issues the pilot encounters, including any potential obstacles for donors registering, such as concerns about financial liability.

47. The general position is that pre-1990 Act donors have no liability for children born where the donations were used in the treatment of married couples. It is, however, theoretically possible that a donor could be regarded as a parent under the Child Support Act 1991 if the child born is aged 19 or under and in full time non-advanced education and the donation was given to a couple who were not married, or where the husband could prove that he did not agree to the use of a donor. It is extremely unlikely that such a case would ever arise. Should it do so, the individual circumstances would be considered by the Child Support Agency. We have advised UK DonorLink to make this clear to potential applicants.

12 'Family-balancing' refers to the selection of the sex of a child in order to balance the ratio of children of one sex to another within a family.

Recommendation 32

We have sympathy with the view that if children born following donor insemination have a right to know their genetic parents, donors have some rights to non-identifying information about any children born as a result of their donation. We recommend that the Government address this anomaly in its review of the HFE Act. (Paragraph 151).

48. In 2004 the HFEA updated its advice to licensed clinics, clarifying that certain information may be disclosed to donors as long as it does not identify the children born or their parents (HFEA Chair's letter CH(04)07). We will seek wider public views on whether requirements for the provision of information to donors should be expressly included in legislation.

Recommendation 33

We regret the Department's poor use of evidence in policy-making and its failure to commission and have published the necessary research underpinning its decision on the removal of donor anonymity. (Paragraph 154).

49. The Government does not accept that its policy on donor anonymity was based on poor use of evidence, or that the information on which the policy was based was not made publicly available. The Department of Health carried out a public consultation on the provision of information about gamete and embryo donors from December 2001 to July 2002. This was followed by a questionnaire to licensed clinics and, through them, their donors, from February to June 2003, and correspondence with experts on the position in other countries.

50. The response to the public consultation was summarised on the Department of Health's website[13]. A summary of the responses to the questionnaires issued to clinics and donors was given by the Public Health Minister when she spoke at the HFEA Annual Conference in January 2004. This speech was also available on the Department's website.

51. Following these consultations and evidence gathered, we took a decision that it was fundamentally wrong to perpetuate the situation whereby donor-conceived people were denied access to information about their donor that was held on the HFEA's national database. Parliament was therefore asked to approve the regulations removing anonymity from future donors, which it did after debate in both Houses.

Recommendation 34

Given the threat to donor supply, it would have been better to have attempted to conduct research on parental attitudes to secrecy in the context of anonymity versus identifiable donors before changing the system entirely to one where anonymity is ended. (Paragraph 157).

13 www.dh.gov.uk/Consultations/ConsultationsLibrary/fs/en

52. The information that we have received from clinics and from the National Gamete Donation Trust on the availability of gamete donors indicates that any threat to the donor supply has arisen because of:

    - uncertainty as to whether anonymity would be removed
    - unwillingness to recruit while that certainty remained, and
    - a lack of public awareness that donors were needed.

53. We do not accept that research on parental attitudes to secrecy in the context of anonymity versus identifiable donors would have remedied this situation. Neither do we believe that parental secrecy will increase as a result of the removal of anonymity, although we accept that some parents have reacted, initially at least, by saying that they will not tell.

54. Research by Professor Susan Golombok published in 2004[14] reports that, contrary to the findings of earlier investigations, the parents of donor-conceived children appear to be becoming more open towards disclosing the donor conception to the child. It is our view that the secrecy surrounding assisted conception has greatly reduced in recent years, and that parents are more inclined towards open discussion with family, friends, and their children. The Parenting Fund established by the Department for Education and Skills is funding the Donor Conception Network to produce materials which will help parents to tell.

Recommendation 35

While the arguments for and against changing the status of donors are complex, opinions seem to centre on the relative weight given to the pain of infertility and the welfare of the offspring. Despite this, most would agree that, in principle, openness is a good thing. The task is to promote as much openness as possible without sacrificing the availability of donated gametes. In our view the benefits from the removal of anonymity are not such that the change justifies the likely impact on the number of donors. We therefore favour a twin track approach. While patients and donors should be aware of the benefits of openness and the regulator should provide for those who wish to adopt this strategy. (Paragraph 158).

55. The Government recognises that infertility causes great distress to many couples. It is also our view that, in the context of the perpetuation of donor anonymity, the rights of the child are first and foremost. We considered the option of the twin track system, whereby the parents choose either an identifiable or an anonymous donor, but rejected it on the grounds that (a) it would give preference to the wishes of the potential parents ahead of the interests of the child and (b) it would be inequitable to introduce a two-tier system of rights of access to information for the children.

Recommendation 36

We have been told that, the earlier the child is told that they were born from donor gametes the better, yet parents wishing to tell their child that he or she was born using donor gametes may wish to avoid telling them if they then are unable to know anything about the donor. We recommend that certain non-identifying information is available to the child so that they can request it upon being told by their legal parents that they were conceived using donor insemination. (Paragraph 159).

56. Parents are given non-identifying information about the donor at the treatment stage. We accept that in some cases, as the parent prepares to tell the child that he or she is donor-conceived, they may have lost or forgotten some of the information about the donor. We do not think that it is appropriate for the child to approach the clinic where the parents were treated to ask for information about the donor, since the child has no first hand links with that clinic. We also do not think that it is appropriate for the HFEA to give the information which they hold to children of a young age. However, parents may contact the clinic, or if essential the HFEA, to ask for the non-identifying information about the donor, which they can then pass to the child.

57. We will seek wider public views on whether the age at which donor-conceived people are able to request non-identifying and identifying information about their donor from the HFEA should be reduced from age 18 to age 16.

Recommendation 37

In recognition of concerns about the supply of donors, the Department of Health has launched a PR campaign to recruit new donors. By the time revised legislation is placed before Parliament, data should be available that give an indication as to whether the removal of anonymity will have a long-lasting effect on the supply of donors. With this information, Parliament can decide to what extent the removal of anonymity is a price worth paying. (Paragraph 160).

58. We have accompanied the removal of the anonymity of sperm and egg donors donating from 1 April 2005 with a campaign for public awareness of the value of sperm and egg donation. There has been a healthy response to this campaign, which featured the National Gamete Donation Trust (NGDT) as the response line funded by the Department of Health. The NGDT will continue working with clinics and donors to promote local activity which raises awareness of donation, and we will continue to monitor the situation.

Recommendation 38

We look forward to the results of the HFEA's consultation on the remuneration of embryo and gamete donors. We are concerned that the HFEA should be placed in a position in which it is forced to make decisions that could provide an incentive or disincentive to donors. This is a political decision best left to Parliament. (Paragraph 162).

59. The EU Tissue Directive includes a statement of principles governing tissue and cell donation. Article 12 says that Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells but donors may receive compensation.

60. The Government intends to seek views on whether the appropriate level of compensation for donors should be set by the HFEA or by Parliament by means of regulations.

Counselling

Recommendation 39

While we believe that clinicians should adopt a more sympathetic attitude to infertility counselling, counsellors must work harder to develop an evidence base to support their practice. Only in this way can they hope or deserve to receive the respect of their clinical colleagues. We see no role for legislation or regulation in facilitating this process. (Paragraph 168).

61. The Government is aware of evidence of the benefits of counselling in other settings and believes that counselling can play a valuable role in helping patients make informed reproductive decisions and understand the implications of those decisions.[15]

62. At present the law requires that couples undergoing fertility treatment must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps. The Government intends to consult on whether that requirement should continue in place.

Licensing for clinical trials and training

Recommendation 40

The HFEA is able to attach conditions to any licence that it awards and it could already use its existing licensing system to ensure that certain techniques were only used as part of a clinical trial. We recognise that powers to award a clinical trials licence might have advantages for the HFEA but we would be nervous about the creation of any further bureaucratic hurdle introduced to the setting up of clinical trials. (Paragraph 172).

Recommendation 41

It is not appropriate that embryos donated for research should be used to train staff and it could be argued that the HFEA is acting illegally by awarding research licences in the knowledge that the primary purpose is training. Furthermore, training in the handling of embryos should not be limited to those centres that are undertaking research. Training staff to handle embryos for the purposes of providing treatment should be possible under treatment licences as long as it is made clear to donors of embryos what they will be used for. (Paragraph 173).

15 Department of Health, Treatment choice in psychological therapies and counselling: evidence based clinical practice guidelines, 2001.

63. The Government will give further consideration, through its review of the HFEA Act, as to whether the current licensing structure requires any amendment in order to enable the adequate training of practitioners and the appropriate evaluation of new clinical techniques.

Stem cell research

Recommendation 42

The budget allocations for the 2004 Spending Review were published in March 2005 without any specific reference to stem cell research. We recognise that the Research Councils have no interest in investing in research teams if they have no interest in sustaining them in the medium term. However, we recommend that they monitor the success of applications in this area made in open competition and bid for ring-fenced funds in future Spending Reviews if funding in stem cell research projects declines (Paragraph 181).

64. On 7 March 2005 the Government announced that UK biotechnology funding – including stem cells research and DNA based medicines – will rise to over £1 billion over the next three years. On 15 March 2005 the Government announced the establishment of the UK Stem Cell Initiative, involving a panel of experts under the chairmanship of Sir John Pattison. The panel includes membership from the Research Councils and is charged with developing a cohesive vision for UK stem cell research over the next decade. This initiative will have input from both the public and private sectors and will produce a costed strategy for this research in the UK from 2006-2015. The report and recommendations from the Initiative will help to guide future Government support for this area of research.

Penalties

Recommendation 43

That the embryo only gradually acquires human rights is a widely accepted view. In this light, the maximum sentence of 10 years for breaching some of the prohibitions in the HFE Act seem unduly harsh. (Paragraph 183).

65. In passing the Reproductive Cloning Act in 2001, Parliament decided that the maximum sentence of ten years imprisonment, or a fine or both, was appropriate for reproductive cloning, and the Government has no plans to change that.

66. However, we note the Committee's concerns that the same penalty for offences under the HFE Act may be unduly harsh, and we will consider in our review of the HFE Act whether the penalties should be reduced.

Person responsible

Recommendation 44

The legal role of the person responsible is outdated. While the law did not confer liability on the person responsible for the misdemeanours of a member of staff, it still seems sensible to separate responsibility in respect of compliance with the HFE Act and compliance with technical standards. Standards would become the responsibility of the Trust Chief Executive (or equivalent in the private sector) while responsibility for compliance with the provisions of the HFE Act would be retained by a senior member of the clinic. (Paragraph 184).

67. The Government is not persuaded of the merits or practicality of attempting to move responsibility for compliance with technical standards away from the person responsible. The requirements in the HFE Act and the standards for clinics are not easily separated, and the person responsible should be the person best placed to see that both are complied with.

68. The EU Tissue Directive will require the designation of a 'responsible person' for tissue establishments carrying on activities within the scope of the Directive. The role of the 'responsible person' will largely comprise securing compliance with the safety and quality standards required under the Directive, which will be incorporated within the HFE Act insofar as they concern gametes and embryos.

69. The Government intends that the role of 'responsible person' as required by the Directive will be incorporated into the role of the person responsible for establishments licensed under the HFE Act.

Encouraging good practice

Recommendation 45

We agree that the regulator needs a wider range of sanctions but we are concerned that the emphasis is on penalty and not on improving standards and systems. The incompetent and the unethical needs to be closed down but the vast majority in the middle need to operate in a regulatory environment which encourages them to improve. There should be no deterrent to self-reporting. (Paragraph 186).

Recommendation 46

The primary aim of healthcare regulation should be to protect patients. We believe that this can best be achieved by creating a culture in which good practice is encouraged rather than the focus being on penalising poor service. If individual practitioners have performed below acceptable standards, the professional regulators should act in a manner that protects patients. We recognise the Government's efforts to improve professional regulation through the creation of the Council of Healthcare Regulatory Excellence. While these changes need to "bed down", we welcome the commitment to strengthen regulation. (Paragraph 192).

70. The Government agrees that the emphasis of regulation should be on improving standards and systems and the development of good practice, with the principal aim of protecting patients. We believe that this emphasis is increasingly being reflected in the regulation of assisted reproduction in the UK. Changes introduced by the HFEA in 2003, such as responding to incident reports by undertaking a root cause analysis together with the clinic concerned in order to review systems and processes, are evidence of this. They have led to more problem analysis and problem solving rather than the imposition of sanctions, and have reduced the deterrent for clinics to self-report incidents.

71. At the same time, we are glad the Committee recognises that if individual practitioners do fall below acceptable standards, then the regulator must act to protect patients and this may mean imposing sanctions.

Expertise of HFEA members

Recommendation 47

We share the widespread concerns about the extent of the scientific and clinical expertise of Authority members, but recognise that the principle of the lay majority is important and should not easily be discarded. We believe that ultimate authority on issues of public concern should lie outside of the scientific and medical communities. At the same time, it is important that any decisions are informed by the science and medicine. (Paragraph 198).

Recommendation 48

We have sympathy with the view that those with principled opposition to assisted reproduction should be represented and have been unreasonably excluded from a place at the principal forum for debates on assisted reproduction and embryo research. It cannot, however, be a simple matter of reworking the job description for Authority members, since the presence of those opposed to assisted reproduction and embryo research would change the very nature of the organisation. The representation of views needs to be considered as part of a thorough assessment of the regulatory and advisory structures operating in this field. The composition of the regulator must either be substantially reformed or mechanisms found to improve the range and quality of advice it receives. (Paragraph 207).

72. The HFEA is an independent statutory authority comprising members with a range of professional, scientific and clinical expertise together with a lay chair and an overall lay majority membership. The Government agrees with the Committee that it is important that the HFEA has the right balance of lay, scientific and expert input and we keep this continually under review. We also agree that the principle of the lay majority should be retained.

73. Appointments to the HFEA are made by the Secretary of State for Health within the guidance of the Commissioner for Public Appointments and on the basis of the criteria set out in the HFE Act (from 2005 appointments will be made by the NHS Appointments Commission). This process includes the recognition that the HFEA has the role of deciding whether to grant licences for treatment or research projects where it is satisfied that they are necessary or desirable for the purposes laid down in law by Parliament. Whilst there is no bar to opponents of assisted reproduction or embryo research becoming HFEA members, it is clear that a member deciding, on principle, that no licences could be granted would find themselves in an untenable position, and would in fact be frustrating the intentions of Parliament.

74. The HFEA has the flexibility to draw on additional scientific and medical expertise from outside the Authority. It can and does seek advice from recognised experts, including through the use of co-opted members on its specialist sub-committees.

75. The HFEA has also made substantial moves to increase its openness and public accountability and to engage in public consultation to inform its decision-making. In this way, it ensures that it is aware of, and takes account of, the very wide range of views on issues relating to assisted reproduction and embryo research.

HFEA and policy making

Recommendation 49

We have heard that membership of the HFEA has so far been reserved for proponents of assisted reproduction and embryo research. It is therefore not surprising that its individual members would wish to see greater availability of licensable activities. Nevertheless, by promoting gamete donation in its corporate publications it has acted outside its statutory remit and crossed a boundary that risks compromising public trust. (Paragraph 216).

76. The essential role of HFEA members is to regulate assisted reproduction and embryo research activities within the requirements of the HFE Act and regulations. Our view is that HFEA members have carried out their duties effectively and impartially.

77. Section 8(c) of the HFE Act requires the HFEA to provide advice and information for gamete donors. The HFEA therefore has a legitimate interest in gamete donation. We do not regard the approach it has taken in fulfilling this function as being one of promoting donation.

Recommendation 50

It is reasonable for the Authority to draw attention to problematic areas in legislation, indeed it would be negligent if it were not to do so, but there is a clear distinction between drawing attention to problems and inconsistencies and espousing solutions. (Paragraph 217).

78. The Government agrees that it is reasonable for the Authority to draw attention to any problematic areas within the legislation. We also think it is appropriate that the Authority should identify possible solutions. Clearly the Authority needs to be careful that in so doing it is not seen as "espousing solutions".

Recommendation 51

We conclude that the HFEA could not have discharged its statutory duty without developing a policy-making function; nevertheless, any revised legislation should more clearly define the presence or absence of a policy-making role for the regulator. (Paragraph 218).

79. The Government has announced, following the Department of Health's review of its arm's length regulatory bodies, that it intends to replace the HFEA and the Human Tissue Authority with a single authority responsible for the regulation of assisted reproduction, embryo research and the use of human tissue. This will require primary legislation. The Government agrees that this should clarify the extent of the policy making role of the regulatory body.

Recommendation 52

The HFEA must be aware that many individuals and organisations will pore over its statements for evidence of misdeeds. It is unfortunate that it has provided so much ammunition to its critics. As the Science and Technology Committee, we are pleased that the HFEA sees the value of scientific research; however, we accept that it is not its role to encourage licensable embryo research, merely to consider whether applications that it receives conform to the wishes of Parliament. (Paragraph 220).

80. The HFEA operates in a complex and contentious area, where it will often be criticised or challenged whatever decision or statement it makes. The Government's view is that the HFEA does a good job in these difficult circumstances. With regard to embryo research, we agree with the Committee that the role of the HFEA is limited to considering whether applications that it receives conform to the wishes of Parliament.

Code of Practice and the Internet

Recommendation 53

It is right and proper that the HFEA should seek to update the protocols set out in the Code of Practice, which is, in effect, a rule book for centres licensed under the Act. The HFEA has not so far employed the internet to its full potential and we believe that its policy decisions should be consolidated in a single document as far as possible and as quickly as possible into a single digital entity. (Paragraph 225).

81. The Government agrees and will ask the HFEA to explore how it might make fuller use of the internet, and consolidate its guidance. We understand that the HFEA is exploring new format options for its Code of Practice, including an online version, for its next edition in 2006.

HFEA inspections

Recommendation 54

Advocates of the role of the HFEA have argued that it has succeeded in maintaining public confidence in a highly contentious area. If this is the case, it is hard to see how this can be maintained if its inspection processes are attracting sustained criticism. (Paragraph 233).

Recommendation 56

We welcome the HFEA's decision to appoint an in-house professional inspectorate. However, it is important that these inspectors have the confidence of the assisted reproduction community and we recommend that its views are taken into account before appointments are made. (Paragraph 237).

82. The Government recognises that there have been criticisms of the HFEA's inspection processes, and agrees that it is important that they should have the confidence of both the public and professionals. The Government welcomes the HFEA's decision to appoint professional inspectors. We understand that the process for appointing the inspectorate was agreed with the professional bodies and other stakeholders, and we will expect the HFEA to continue to take their views into account in making appointments.

EU Tissue Directive

Recommendation 55

The EU Tissue Directive will provide a welcome impetus to improve and maintain the technical standards in treatment centres. However, we urge the Government and the HFEA to ensure that the standards applied are appropriate and proportionate (Paragraph 235).

Recommendation 90

If the regulator can be assured that external forms of accreditation such as ISO 9001 comply with legislation following the transposition of the EU Directive into UK law, then such accredited facilities should be free to operate without additional scrutiny. (Paragraph 369).

83. The Government agrees that the EU Tissue Directive[16] will have a positive impact on standards and that its transposition must comply with the principles of good regulation. The Government also agrees that the regulator should act so as to minimise the burden of inspection and eliminate duplication of effort.

16 Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

84. The Government plans to consult on the detail of the transposition of the Directive's standards into the HFE Act. In the light of that, the HFEA will consider how best to assess whether treatment centres meet the standards. Forms of accreditation such as ISO 9001 may go some way towards demonstrating compliance with the standards, but may not fully cover the requirements of the Directive.

HFEA openness

Recommendation 57

It is unacceptable for the HFEA to attempt to withhold information relating to licence applications if it has no legal basis for doing so. Information relating to licence applications and licence committees should be made available on the internet as a matter of course. (Paragraph 239).

Recommendation 58

There may have been good reasons why licence committees were unable to hear directly from the patients, but cases must be dealt with sensitively and without needlessly erected bureaucratic walls. We are pleased that the HFEA has decided to adopt a more open policy in the future. (Paragraph 240).

85. The Government agrees that the HFEA should operate in as open and publicly accessible a way as possible, and recognises the improvements that the HFEA has made in this regard. The HFEA now makes inspection records and licence committee minutes available on the internet. The HFEA is subject to the requirements of the Freedom of Information Act 2000 as a 'public authority' within the meaning of that Act.

Research input to HFEA

Recommendation 62

If the HFEA is to retain its current functions, it is important that it has access to the best relevant data to support its decision-making. While research is not defined as part of its remit as such, it should have the budget to fund small scale unlicensable academic studies. (Paragraph 254).

86. The Government does not consider that the HFEA is the appropriate body to undertake or manage research and therefore does not agree that the HFEA should have a budget to fund academic studies. However, we agree that the HFEA should take account of all relevant data in making its decisions.

Recommendation 63

The MRC Working Group contained a social researcher but the report gave little attention to the social impacts of assisted reproduction, despite being cited frequently in HFEA policy documents. We recommend that the HFEA ask the Economic and Social Research Council to set up a working group to look specifically at the social impacts of and attitudes to assisted reproduction. (Paragraph 255).

87. The Government will ask the Economic and Social Research Council (ESRC) to consider whether there is a need to set up a working group as recommended by the Committee.

Recommendation 69

We welcome the setting up of an international Horizon Scanning Expert Panel as a positive step in improving the HFEA's use of evidence. We are unclear why there is not even one social researcher on the panel and urge the HFEA to rectify this. (Paragraph 277).

88. The Government agrees that the HFEA should have access to and make use of the best available data to support its decision-making. The Government also recognises the steps taken by the HFEA to improve its use of evidence, of which the setting up of an international Horizon Scanning Expert Panel is one example.

89. The focus of the panel will be on new technologies and techniques that may be offered to patients in the foreseeable future. It is not clear what contribution a social science researcher could make to this process, which requires scientific expertise in these areas. However, we will explore with the HFEA the scope for input from a social science perspective to complement the work of the panel.

Confidentiality provisions and data for research

Recommendation 64

The confidentiality provisions in the HFE Act have hampered efforts to establish the risks associated with assisted reproduction. We conclude that they are unnecessarily onerous and inconsistent with the widespread use of assisted reproductive technologies. We recommend that the data from the HFEA's register should be applied as far as is possible to research studies. (Paragraph 258).

Recommendation 92

We have recommended that the confidentiality provisions in the HFE Act need to be relaxed. This should be accompanied by efforts to use UK data to inform the international monitoring of the risks of assisted reproduction. (Paragraph 379).

90. The Government agrees that the confidentiality provisions of the HFE Act should be reviewed, and drew attention to this when announcing our review of the HFE Act in January 2004.

Recommendation 65

We have criticised the excessive use of the precautionary principle in assisted reproduction. However, we recognise that there are public concerns about possible adverse risks associated with assisted reproduction. Treatment centres should, as a condition of their licence, maintain a database in a suitable form which is available for peer reviewed research projects. As a result, there will be a justifiable burden on clinics. (Paragraph 263).

91. We agree that there is scope to consider how the data that clinics collect about treatment might best be made available for follow up research. However we do not think it is necessary to introduce a requirement for each clinic to maintain a separate database for that purpose but will seek wider public views. There is already a national database of treatment data held by the HFEA. Funding is being provided by the Government to modernise that database. This will enable clinics to submit their data to the HFEA more effectively in future by electronic interchange and ensure that the data is quality controlled and audited.

92. We will consider how best this data should be made available to researchers in our review of the HFE Act. However, it would be essential to ensure that appropriate safeguards were built in.

Risk assessment of assisted reproduction procedures

Recommendation 67

We take seriously the possible risks of assisted reproduction technologies. For this reason, we encourage research in this area, both to inform professional practice and in order that intending parents can be adequately and appropriately informed of any risk to which they are considering providing consent. (Paragraph 266).

Recommendation 68

No-one wishes to expose patients and children to physical harm or psychosocial stresses, but all medical practice has inherent risks and the only solution is a rational approach to risk assessment and management, coupled with strategies to undertake and apply the results of medical, scientific and social research. (Paragraph 276).

Recommendation 70

By most standards, the safety of IVF lies within the boundaries of acceptability. Nevertheless, any risks must not be underplayed and patients should be made fully aware of them before treatment. We hope the Medical Research Council will look favourably on proposals to undertake national studies to establish the safety and effectiveness of assisted reproduction techniques. (Paragraph 278).

93. The Government recognises that although the safety of assisted reproduction is generally accepted, there is always room for greater reassurance. Our proposal, through our review of the HFE Act, to make HFEA register data more available for researchers should help this. We also note that the HFEA and MRC are currently considering how best to follow up the 2004 report of the MRC Working Group on safety and assisted reproduction.[17]

94. The HFEA's patients' guide to infertility contains information relating to the risks of both regulated and unregulated assisted reproduction techniques, including how to recognise symptoms and appropriate action to take.[18]

17 "Assisted Reproduction: a safe sound future".
18 "The HFEA guide to infertility and directory of clinics 2005/06", HFEA.

HFEA'S data register

Recommendation 66

While the value of the Register for research has been open to question, it should have been able to provide data on the uptake of IVF and donor insemination and success rates to inform policy development on assisted reproduction and its provision. However, in recent years these data have not been published, which is unfortunate. We consider it to be a fundamental role of a regulator to provide information about the industry it is regulating. (Paragraph 264).

Recommendation 74

The issue to be resolved is not whether there should be league tables but how to ensure that the data are sound and provide useful information to patients. Not all of the factors that influence the success of IVF are clearly understood but we see an important role for the regulator in developing metrics. We welcome the HFEA's work on developing better comparators but it should resist publication of success rates for different clinics until it is satisfied that they are not misleading. (Paragraph 295).

95. The Government is aware of the problems that the HFEA has encountered with its data register, largely due to the failure of previous IT systems. It is vital that the information recorded in the register is accurate as young people will be able to seek, from 2008, information on whether they were born as a result of licensed treatment involving a donor. The Government has granted the HFEA funding of £11million over three years from 2003/04 for the redevelopment of its data register, and the audit and validation of previously recorded data.

96. It would be inappropriate for the HFEA to publish outcome data without sufficient assurance of their accuracy. The Government agrees that outcome data should be published provided that they are sound and not misleading.

HFEA'S role as a regulator

Recommendation 71

We welcome the changes in the funding arrangements for the HFEA, which recognise that the HFEA, as presently constituted, has a wider duty to the public beyond its role as a regulator. (Paragraph 279).

Recommendation 72

The principles of good regulation adopted by the Better Regulation Task Force are appropriate and valuable. We regret that in many areas the HFEA falls short of these ideals. We recognise that the HFEA has improved its performance but it has been stretched by too much poorly targeted regulation. This needs to be addressed by refocusing its efforts. We will discuss our solutions in Chapter 9. (Paragraph 290).

97. The Government is committed to the principles of good regulation – proportionality, accountability, consistency, transparency and targeting – and has taken the steps necessary to ensure that the HFEA is appropriately resourced to fulfil its obligations.

98. The HFEA has undoubtedly improved its performance over recent years. However we recognise there is always scope for further improvement and we expect the HFEA to continue to refine and target its regulatory procedures.

Value of services offered by clinics

Recommendation 73

We have heard concerns that some of the services being offered to patients in IVF clinics are not justified by evidence of their value. We believe that clinics, private and NHS, must make it clear when they are offering services and treatments that lie outside the NICE guidelines. Practitioners need to be aware that their patients are desperate for a child and vulnerable to exploitation. We recommend that the Healthcare Commission prioritise its activities in this area. (Paragraph 292).

99. The Government agrees that it is important that patients are appropriately informed. We believe that the HFEA is better placed to ensure that infertility clinics do so than the Healthcare Commission. The HFE Act currently includes provisions designed to ensure that patients are fully informed about their treatment, have a suitable opportunity to receive counselling on its implications, and that they give effective consent. These requirements are supplemented by professional good practice – for example in relation to matters such as advertising of services – and by the HFEA's code of practice and patients' guide to infertility.

100. We will give further consideration to whether patients should be explicitly informed that a particular service or treatment lies outside the National Institute for Clinical Excellence's guideline on infertility.[19]

International standing of UK assisted reproduction services

Recommendation 75

Despite being a pioneer in IVF, the UK lags behind many of its European neighbours in quality of the treatment it offers. We believe that, while regulation is not necessarily an appropriate tool to improve standards, the Healthcare Commission has a role in identifying the reasons why some other countries perform better than we do as a means of underpinning changes in UK practice. (Paragraph 297).

19 "Fertility: assessment and treatment for people with fertility problems", NICE, February 2004.

Recommendation 96

The Government claims that our regulation of assisted reproduction is highly regarded with little substance to support this view, which betrays a worrying complacency. We recommend that the Government, as a first step in its review of the HFE Act, conduct a review of regulatory models overseas and their effectiveness in maintaining public confidence, protecting patients and promoting safe and effective treatment. Given that the Progress Educational Trust has made a start, it would be well placed to continue this work, with appropriate funding, on behalf of the Department of Health. (Paragraph 389).

101. The Government does not accept that the UK "lags behind many of its European neighbours". As the Committee indicates, the information collected by the European Society for Human Reproduction and Embryology (ESHRE) is based on different data collection systems in individual countries with variable degrees of coverage – not every clinic is necessarily included in national surveys – and different definitions for outcome data. By contrast, the data submitted from the UK covers all licensed clinics in this country and is verified by HFEA audit.

102. However, we do accept the need to seek consistently to improve standards. To this end we will be introducing the EU Tissue Directive into UK law, which has the aim of standardising assisted reproduction quality and safety requirements across all EU countries. We will also take account of regulatory models overseas in our review of the Act.

Professional bodies and standards

Recommendation 76

We welcome the increased responsibility taken by professional bodies to draw up and maintain guidelines on clinical and laboratory standards. (Paragraph 299).

Recommendation 89

We see great merits in the professional bodies taking control of the technical and management standards and welcome the offer of the Royal College of Obstetricians to take responsibility under the auspices of the regulator in drawing up and maintaining these standards for centres concerned with the provision of storage or treatment services in compliance with the EU Tissue Directive. (Paragraph 368).

Recommendation 101

Professional bodies under the auspices of the Royal College of Obstetricians and Gynaecologists would draw up technical standards for clinics offering assisted reproduction and undertaking embryo research as a basis for accreditation. The guidelines should set out how assisted reproduction techniques should be undertaken but would not specify what those techniques would be used for. These standards should be consistent with the EU Tissue and Cells Directive (Paragraph 395).

103. The Government welcomes the proactive role of the professional bodies in maintaining high standards and promoting best practice. The professional bodies have played an important role in informing the content of the HFEA's code of practice, and behaviour in accordance with professional guidelines and standards is regularly cited in the code. A working group drawn from a number of professional bodies is currently developing standards as a basis for accreditation, and has provided expert input to the negotiation of the requirements of the EU Tissue Directive.

104. The Government will consider, as part of its review of the HFE Act, whether the role of professional bodies in setting standards for infertility clinics should be placed on a more formal footing.

Abortion legislation

Recommendation 77

We call on both Houses in the new Parliament to set up a joint committee to consider the scientific, medical and social changes in relation to abortion that have taken place since 1967, with a view to presenting options for new legislation. This committee should be broadly based and should include nominees from the Commons Select Committees for Science and Technology and Health and the Lords Science and Technology Committee. (Paragraph 308).

Recommendation 78

We recommend that any new legislation introduced to amend the HFE Act should not include abortion, which should be dealt with in a separate Bill. (Paragraph 309).

105. The Government has no plans to change the law on abortion. If a joint committee is set up to look at this issue, the Government will consider its recommendations. However, it is accepted Parliamentary practice that proposals for changes in the law on abortion have come from back bench members and that decisions are made on the basis of free votes, with members and peers voting according to their own beliefs and values.

106. We agree that any changes to the abortion legislation should be kept separate from changes that may be necessary to the HFE Act as a result of our review.

Surrogacy

Recommendation 79

We recommend that the Department includes with its review of the HFE Act an assessment of surrogacy arrangements. This should use the Brazier Report as a starting point and consider what developments there have been since 1998. We regret the Government's inaction. Consideration should be given to introducing separate legislation covering surrogacy. (Paragraph 312).

107. The Government recognises that surrogacy arrangements may involve assisted reproduction treatments and raise issues relating to parental status which are dealt with in the HFE Act. As Professor Brazier surmised in her evidence to the Committee,[20] the Government has had to prioritise other matters above the review of surrogacy. However, we will consider the need to review surrogacy arrangements in the context of the review of the HFE Act.

Introducing new legislation

Recommendation 80

We recommend that the Government publish any revised Bill on assisted reproduction and embryo research in draft. We recommend that this Bill, and any new Abortion Act, be subject to pre-legislative scrutiny. (Paragraph 313).

Recommendation 81

We recommend that the Parliamentary parties should give a clear undertaking that Members will be given a free vote on any new legislation concerning assisted reproduction and embryo research. (Paragraph 314).

108. The Government notes the recommendation that any revised Bill on assisted reproduction and embryo research should be published in draft, and should be subject to pre-legislative scrutiny. The Government accepts that the benefits of wide consultation and scrutiny are especially appropriate to this ethically-contentious and technically complex area.

109. The Government also notes the recommendation that Members should have a free vote on any new legislation. Free votes have historically been a feature of parliamentary debates in this area. However, this is a matter for the individual political parties.

Parliament's role

Recommendation 82

In our view, Parliament's ability to revisit contentious issues relating to the creation of new life and the permissible uses of human embryos is vital. We recommend that new legislation is more explicit and provides Parliament with greater powers to debate and amend legislation. We propose mechanisms for achieving this in Chapter 9. (Paragraph 315).

Recommendation 87

We remain convinced that a larger role for our democratically accountable Parliament would give the public greater confidence that the big ethical issues of the day are being given adequate attention. (Paragraph 356).

20 Ev 121, Fifth Report of Session 2004-5, Volume II, Oral and written evidence.

Recommendation 102

We have argued for greater Parliamentary oversight over issues relating to assisted reproduction and embryo research. To achieve this we propose a new Parliamentary Standing Committee on Bioethics. This would undertake annual scrutiny of the Regulatory Agency for Fertility and Tissues, make recommendations on the need to amend or introduce legislation and scrutinise draft legislation brought before Parliament within its remit. (Paragraph 398).

110. The Government share the Committee's view of the value of airing and debating bioethical issues in Parliament. Indeed, Parliament is already very much engaged in this work, and the Government is not convinced that the creation of a new Parliamentary Bioethics Commission is actually necessary. We are, however, willing to give further consideration to the appropriate level of Parliamentary control over delegated powers under the legislation, and to look at whether new structures would help facilitate further Parliamentary oversight.

Clinical ethics committees

Recommendation 84

There are merits in the creation of a nationally coordinated network of clinical ethics committees to parallel the arrangement for local research ethics committees. Should the evaluation of these committees demonstrate their value, they should be provided with national guidelines for their conduct in the area of assisted reproduction but their decisions should be directed to the needs of patients and their families and the concerns of health care professionals. (Paragraph 345).

111. The Government agrees that there may be merit in local clinical ethics committee support to aid clinical decision-making, and in the establishment of a national network. As the Committee recognises, whereas some assisted conception clinics have a dedicated clinical ethics committee, the national provision of such committees is uneven at present. However, the Government is not convinced that attempting to direct centrally the conduct and decisions of local clinical ethics committees in the manner recommended is an appropriate role for central Government.

Human genetics, fertility and tissue commission

Recommendation 85

We believe that the Government is correct that smaller advisory committees with specific briefs would be more effective. Nevertheless, we favour the rationalisation of these committees where there is clear overlap and human genetics and embryology fall into this category. We recommend the formation of a single commission to develop policy issues relating to the assisted reproduction, embryo research and human genetics. (Paragraph 352).

Recommendation 86

Any national policy-making committee should not attempt to interfere with individual clinical decisions. If the value of local clinical ethics committees can be established, they should be given a defined brief that clearly distinguishes their role from the Commission, which should issue guidelines for their operation. (Paragraph 354).

Recommendation 88

There is sufficient overlap between the policy and advisory functions of the HFEA and the Human Genetics Commission to provide a strong case for merger. (Paragraph 365).

Recommendation 103

We propose the creation of a new Human Genetics, Fertility and Tissue Commission would expand the remit of the Human Genetics Commission to include the issues currently within the domain of the HFEA and the relevant areas from the Human Tissue Authority. The bodies would provide advice and recommendations on issues where it considered that there were societal implications, such as selection for social reasons and preimplantation tissue typing, but would not provide clinical guidance. It would be informed by public consultations and could commission social science research. (Paragraph 399).

112. The Government considered whether to establish a single commission with a remit covering the entirety of bioethics issues as part of the Department of Health's review of its arm's length bodies. This was rejected, after careful consideration, on the basis that the present distributed model of advisory bodies with more specific briefs remained the best option as it enables specific bioethical issues to be addressed by dedicated groups with the appropriate expertise and sufficient time to devote to the issue.

113. The Government does support, however, the rationalisation of regulatory or advisory bodies where there is clear overlap or clear advantages from merger. The Government has announced its intention to replace the HFEA and the Human Tissue Authority with a single body responsible for the regulation of human tissue including gametes and embryos. This will be known as the Regulatory Authority for Tissue and Embryos (RATE).

114. The new Authority requires primary legislation. We intend that this legislation will set out the policy in relation to human tissue and embryos and assisted reproduction clearly and comprehensively. It will also give Parliament a greater role in keeping the law up to date through means of secondary legislation. The policy making role of the new Authority will therefore be limited.

115. The Government is not convinced of the merits of including the Human Genetics Commission (HGC) with the advisory functions of the HFEA and the HTA (which will move to RATE). We consider that the HGC is doing extremely valuable work in the area of human genetics and we would not want to see this diluted or diminished in any way. However the Government is committed to ensuring that advice is provided by the organisation best placed to do so, so we will keep this question under review.

New Regulatory Authority

Recommendation 91

The creation of the Regulatory Authority for Fertility and Tissue seems to be the result of political pressure to be seen to be reducing bureaucracy rather than a logical move. Nevertheless, we share the Department's wish to see fewer appendages to central Government and recognise that the merger of the regulatory functions of the HFEA and the HTA has its merits as long as its implementation recognises that there are big differences in the activities they regulate, as well as similarities. However, its activities should be restricted to the oversight of assisted reproduction to technical standards and quality management. (Paragraph 376).

Recommendation 97

We have argued that there should be a balance between the freedom of individuals to make their own reproductive choices and the legitimate interests of the state, but that any intervention into reproductive choice must have a sound ethical basis and also take into account evidence of harm to children or to society. We propose that the current regulatory model, which provides the HFEA with a large amount of policy-making flexibility, should be replaced with a system which devolves clinical decision-making and technical standards down to patients and professionals while at the same time strengthening Parliamentary and ethical oversight. This system has three strands: a dedicated Government regulator to ensure high standards of treatment; professional regulation to ensure the highest level of conduct by practitioners; and a system of ethical oversight. (Paragraph 390).

Recommendation 100

Legislation will create the Regulatory Agency for Fertility and Tissues funded by fees from accredited facilities. It would have an advisory body drawn from the relevant professional bodies. The Agency will:

a) Ensure that clinics using procedures covered by the Act are appropriately accredited, through the use of an in-house inspectorate or recognised external accreditation bodies;

b) Regulate gamete and embryo donation and donation services, including the maintenance of a national database;

c) Set maximum limits for multiple pregnancies for treatment centres using procedures falling within the legislation; (Paragraph 395.c))

d) Collect and analyse outcome data;

e) Validate new materials or processes for the handling of embryos or gametes;

f) Provide information to patients, including the cost of treatment. It could intervene to ensure that patients were not charged excessive costs by private clinics;

g) Ensure that research proposals have received adequate ethical and scientific review and publish a lay summary of all approved research projects covered by the legislation;

h) Be supported by an advisory body for technical standards under the auspices of the Royal College of Obstetricians and Gynaecologists and the Royal College of Pathologists.

i) Undertake the role currently envisaged for the Human Tissue Authority. There should be provision for secondary legislation to bring regulation of non-reproductive tissues into line with that for assisted reproduction and embryo research in consultation with relevant professional bodies and accreditation services. (Paragraph 394).

116. The Government notes the Committee's views about the role of the proposed new regulatory authority. We announced our decision to replace the HFEA and the Human Tissue Authority (HTA) with a single regulatory body as part of a review of the Department of Health's arm's length bodies – those stand-alone national organisations sponsored by the Department of Health that undertake executive functions. This is part of a wider programme to improve efficiency and to release more resources for the delivery of frontline NHS services to patients. We are pleased that the Committee supports the need to reduce the number of arm's length bodies and accepts that the merger of the HFEA and HTA has merits.

117. The merger of the HFEA and HTA will create a single body responsible for the regulation of the whole range of human tissue, embryos and assisted reproduction. It will also be the single competent authority responsible for overseeing the requirements of the EU Tissue Directive. It was originally intended that the new body would be called the Regulatory Authority for Fertility and Tissue (RAFT), but it is now proposed that it will be called the Regulatory Authority for Tissue and Embryos (RATE).[21]

118. The creation of RATE will require primary legislation, and the Government will therefore present to Parliament in due course its proposals for the role, remit, composition and powers of the authority. We agree with the Committee that so far as possible clinical decision making should be left to patients and professionals, that professional regulation is essential and that Parliamentary oversight should be strengthened. We are grateful to the Committee for its specific recommendations (in paragraph 394) about the remit of this new body. We will certainly take these into account in drawing up the new legislation and we would expect to include most if not all of them.

International standards

Recommendation 93

We see major advantages in creating international standards in the handling and export of human gametes and embryos to improve the consistency and quality of procedures, protect those at risk of exploitation and improve the monitoring of treatments and risks. (Paragraph 381).

21 This will avoid potential confusion with the Restoration of Appearance and Function Trust.

119. The Government agrees. The EU Tissue Directive will help to address this by introducing common safety and quality standards for tissue establishments across the EU, including in regard to import and export.

Recommendation 94

We believe that any attempts to curtail reproductive tourism would not be justified by the seriousness of the offence. Moreover, it would be impossible to enforce if the treatment was legal in the country concerned. Nevertheless, anyone considering such a course of action should be aware of any risks involved. It would be inappropriate for the HFEA to encourage patients to go overseas for treatments that were either prohibited or prevented in the UK; however, we consider the HFEA's guidance to be misleading and complacent. We recommend that it provide more detailed guidance on treatment overseas based on evidence not on prejudice. (Paragraph 385).

120. The Government tends to agree with the Committee that attempts to control reproductive tourism would be extremely difficult to enforce and probably not justified. However, there is no question of the HFEA encouraging patients to circumvent UK law by travelling to countries outside of its regulatory jurisdiction. The HFEA, through its work with the European Society for Human Reproduction and Embryology (ESHRE), is working closely with the European fertility sector in order to advance common standards and regulatory coherence. The purpose of the HFEA's current guidance is to highlight specific issues that patients seeking treatment abroad should consider. The Government will ask the HFEA to consider how patients might be better informed about specific safety or legal concerns associated with treatment abroad.

Recommendation 95

Charters, declarations and treaties no doubt keep diplomats busy and fulfilled but there are some ethical issues which are the domain of nation states and cultures. We should respect the cultures and desires of others and not seek to impose our own ideas. Such charters can only produce vague, lowest common-denominator agreements that are of questionable clarity and dubious effectiveness. Further attempts should be resisted until legislation and regulation are more widespread and the common threads can be identified. (Paragraph 387).

121. The Government recognises the difficulties inherent in attempting to frame international agreements in this area due to the different cultural traditions in other countries, and agrees that many of the issues that arise are matters more appropriately resolved by individual nation states.

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